Expert opinion vs. empirical evidence
The precautionary principle applied to GM crops

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Expert opinion is often sought by government regulatory agencies when there is insufficient empirical evidence to judge the safety implications of a course of action. However, it can be reckless to continue following expert opinion when a preponderance of evidence is amased that conflicts with this opinion. Factual evidence should always trump opinion in prioritizing the information that is used to guide regulatory policy. Evidence-based medicine has seen a dramatic upturn in recent years spurred by examples where evidence indicated that certain treatments recommended by expert opinions increased death rates. We suggest that scientific evidence should also take priority over expert opinion in the regulation of genetically modified (GM) crops (see Box 1). It might be argued that prohibiting or delaying the approval of a (GM) crop based on expert opinion suggesting unreasonable risk (in the face of a weight-of-evidence to the contrary) does not have such dire consequences. However, the delayed introduction of nutritionally enhanced GM crops, such as “golden rice,” has been estimated to cause a great many deaths and cases of serious sickness as a result of malnutrition.2

Here we discuss two examples where regulation of GM crops based on expert opinion is in conflict with the mass of scientific evidence. The first is the regulatory requirement for crop composition studies (for traits that are not expected to alter plant metabolic pathways). These studies are conducted at great expense (over one million US dollars per study) to investigate whether the insertion of transgenic DNA has unexpectedly caused adverse changes in the composition of the crop. Diverse GM crops, representing well over one hundred GM events, have been tested in such studies without a single case of an adverse effect being detected.3 Furthermore, transgenesis is consistently characterized by fewer unintended changes compared with traditional breeding, based on the overwhelming scientific evidence on variation in composition among conventional and GM crop varieties.4

Combining the findings of lack of adverse changes from unintended effects

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of transgenesis with our knowledge of how conventional breeding alters crop composition argues against a regulatory requirement for specific studies to assess the composition of each new GM event. For many crops improved through GM technology (e.g., soybean, rice, and maize), not a single conventionally bred variety has been restricted from use based on crop composition over their thousands of years of genetic manipulation and consumption. For other crops, the components known to be compositionally hazardous (e.g., glycoalkaloids in white potatoes) are routinely assessed in new cultivars, irrespective of whether they are GM or not.3 This empirical evidence appears to be ignored by regulations in favor of 20-year-old precautions4 as evidenced by the increase in the complexity of some regulatory requirements for compositional studies.5 In addition to the cost of these trials, lengthy delays in approvals often originate from small but statistically significant compositional differences that have no biological or safety relevance and are expected to occur due to intra-varietal variation when a crop line is derived from a single plant and compared with the composite generics of the originating cultivar.9 This regulatory requirement becomes even more scientifically untenable in jurisdictions where compositional studies must be repeated when two separate and unrelated GM events, for which compositional safety has been previously demonstrated, are combined through traditional crossing.

A second example, where the preponderance of evidence indicates negligible risk, is the evaluation of potential horizontal transfer of plant transgenes to bacteria. Our expanding knowledge of plant and microbial genomes reveals that transfer of prokaryotic genes to eukaryotes has occurred in an evolutionary time frame, but that the converse (transfer of functional genes from eukaryotes to prokaryotes) appears to have happened rarely, if at all, despite millions of years of opportunity.10 An example of horizontal transfer of a functional gene from a plant to a microbe may eventually be found; however, it is clear from direct evidence that such transfers must be extraordinarily rare.8,9 When the negligible potential for gene transfer is coupled with the minimal potential hazard (should transfer actually occur), the overall risk becomes vanishingly small.9 The regulatory requirement to evaluate the risks of horizontal transfer from plants to bacteria7 once again seems to distort the intent of the precautionary principle in the face of overwhelming evidence that mechanistic barriers to this type of gene transfer exist.7

Other instances of expert opinion leading to regulatory requirements for GM crops that are in conflict with the preponderance of current scientific evidence are not difficult to identify. Examples include studies of the digestive and heat stability of newly expressed proteins to predict allergenic potential, and evaluations of weediness to assess whether highly domesticated crops, such as maize, will become invasive due to the presence of GM traits.11,12 Evidence-based medicine has been adopted widely to overcome the often erroneous recommendations that can arise from expert opinion. We encourage regulatory authorities to consider this paradigm for the regulation of GM crops so that this technology can be evaluated more efficiently, and when found valuable, more widely applied to address environmental, nutritional, and food-production needs. When scientific evidence is ignored in favor of the expert opinion that shaped some government regulation for GM crops, then the precautionary principal is being distorted to provide spurious scientific rationale for restricting the use of this approach for crop improvement. The implications of regulatory delays for GM crops are often presented in the abstract, such as lost opportunities for innovation; however, the costs are real. Ingo Potrykus put it starkly when discussing delays in approving golden rice: “I hold the regulation for genetic engineering responsible for the death and blindness of thousands of children and young mothers.”13

Disclosure of Potential Conflicts of Interest

The authors are employed by companies that develop and market transgenic seed.
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