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Roundtable

Response to comments by DiGiovanni and Kevan on "Session V: Estimating Likelihood and Exposure", by Zaida Lentini, *Environ. Biosafety Res.* 5 (2006) 193–195

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DiGiovanni and Kevan (2008, *Environ. Biosafety Res.* 7: 105–108) commented extensively on the empirical approach that I and my co-authors took in our previous modeling of pollen-mediated gene flow in maize (Gustafson et al. (2006) *Crop Sci.* 46: 2133–2140). As we detailed in that original paper, gene flow is a highly complex process that necessarily requires at least some level of empiricism in order to adequately quantify all of the biological, meteorological, and physical phenomena that are involved. DiGiovanni and Kevan favor a mechanistic modeling approach, and they proposed a number of potential advantages for such a method over our entirely empirical technique. However, the 20 m buffers we had proposed based on our empirical model continue to be supported by the rapidly growing body of experimental data on maize gene flow that has now been collected in Europe and elsewhere around the world. This does not mean there is no place for mechanistic modeling of gene flow, but it does suggest that properly implemented empirical approaches have a valid role to play. They offer a degree of simplicity and practical utility that is not available from more complicated approaches.

Keywords: maize / transgenic / gene flow / models / European Union

INTRODUCTION

First of all, I thank both the Editor and Zaida Lentini for the opportunity to respond to the issues raised in the comments made by DiGiovanni and Kevan (2008, in this issue), many of which were aimed at the empirical modeling approach to pollen-mediated gene flow taken by me and my co-authors in our recent paper (Gustafson et al., 2006). As we discussed therein, gene flow is a highly complex process involving a host of potentially chaotic physical, biological, and meteorological phenomena, many of which are far beyond the reach of any fully mechanistic physical model to simulate. To cite just one example, the issue of biological pollen compatibility is not understood in a quantitative way for all possible pairs of maize hybrids and will therefore forever remain an empirical "fudge factor" in whatever mechanistic model is proposed. From a practical viewpoint, therefore, it is clear that at least some degree of empiricism is necessary in order to have a gene flow model with a reasonable degree of accuracy.

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NEW DATA SUPPORT ORIGINAL MODELING

As for our particular implementation of an empirical modeling approach, DiGiovanni and Kevan stated that "the onus still remains on Gustafson to substantiate, numerically, that those data are truly 'representative' of the situation in the EU, and indeed in other locations and other conditions in North America". I wholeheartedly agree that geographically relevant empirical data is important, and in fact, the scientific community has responded. There has been a rapid increase in the number of published maize gene flow field studies since we performed our original modeling work, both in Europe and in North America (Bannert, 2006; Bannert and Stamp, 2007; Bénétrix, 2005; Byrne et al., 2007; Della Porta et al., 2006; Devos et al., 2005; Goggi et al., 2006; JRC, 2006; Langhof et al., 2008; Messeguer et al., 2006; Ortega Molina, 2006; Weber et al., 2006; Weekes et al., 2007). As these data have appeared and as the number of studies increases, I have found that our empirical model continues to provide gene flow values that are entirely consistent with this rapidly growing body of observational data. The weight of evidence fully supports the bottom-line conclusions of the empirical modeling approach we presented for European maize: any combination of isolation distance and border rows of 20 m or more is predicted to result in gene flow of less than 0.9%, as a blended average for receptor fields 1 ha or larger.

WHAT IS A "REASONABLE WORST CASE"?

Another issue raised by DiGiovanni and Kevan was our definition of "reasonable worst case". We took this to be the 90th percentile of the available field study data, which were themselves generally designed to be worst case with respect to such important issues as synchrony of flowering, proximity and geometry of receptor fields, lack of wind breaks, etc. We stand by this definition and question the practicality of the alternative proposed by DiGiovanni and Kevan, which they define as a "numerically-defined exposure that, with a high degree of certainty, equals or exceeds the maximum of all measured data". This definition is unworkable from a statistical standpoint, because the extreme maximum observed value is a function of sample size. As more data are collected, outliers and perhaps even erroneous data will unavoidably cause the "maximum of all measured data" to continue to climb. This is unacceptable in the real world of regulatory and agronomic risk assessment, where one is forced to conduct quantitative analyses of exposure and risk within the constraints of meaningful statistical certainty.

In evaluating the "reasonableness" of any particular definition of a "reasonable worst case" there is also a practical question that must be asked: What is the actual consequence of having an individual sample above the desirable limit? In the case of agronomic gene flow, there are potential economic consequences, but no known safety concerns, since all of the GM traits in commercial grain production have already been fully evaluated and authorized by the relevant regulatory agencies. Thus, it seems reasonable to select a percentile level for gene flow in maize that is somewhat lower than might be required in a scenario involving impacts on the environment or human health.

MECHANISTIC *VS.* EMPIRICAL MODELING

The final issue raised by DiGiovanni and Kevan is their perspective on the overall relative merits of mechanistic *vs*. empirical modeling. The only disadvantages they list for mechanistic models are that "they tend to be difficult to understand for those who are traditionally trained in the agricultural sciences", and that the development and refinement process "tends to be longer and require more resources". But a complete list of disadvantages would include other key factors. As mentioned previously, such models will continue to require considerable empiricism for many processes (pollen compatibility, air movement within the plant canopy, parameterization for new maize hybrids, etc.). Unlike empirical models, which are known to fit the observed data and can be quickly checked against new data as they are collected, mechanistic models of such complex processes are notoriously difficult and expensive to validate. Consequently, the US EPA has chosen to avoid a lengthy pursuit of validation of some mechanistic models in favor of a mix of mechanistic and empirical approaches as the regulatory task demands. This approach has proven successful, and has been widely accepted by both regulators and the regulated community. Such an outcome seems likely in the case of pollen flow as well, but only time and continued research will tell.

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