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Roundtable

Comment on “Session V: Estimating Likelihood and Exposure”, by Zaida Lentini, *Environ. Biosafety Res.* 5 (2006) 193–195

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We comment on Zaida Lentini’s summary of Session V (titled “Estimating Likelihood and Exposure”) of the 9th International Symposium on the Biosafety of Genetically Modified Organisms. We provide an explanation of the drawbacks of using empirical pollen dispersion models, based largely on the general representativeness of the data used to generate the empirical models. We exemplify the drawbacks by highlighting the limited data used to develop the empirical model of Gustafson (presented in the same Symposium session). We provide a discussion of the meaning of “worst-case” assessments for pollen dispersion, how “worst-case” assumptions are commonly used in environmental impact assessments and how regulators will view worst-case impact assessments differently from the regulated (biotech) community. Finally, we clarify the advantages and disadvantages of mechanistic models and explain why they are often used in preference to empirical models in environmental impact assessments.

Keywords: pollen dispersion / gene flow / mechanistic models / empirical models / data representativeness / worst-case / environmental impact assessments

INTRODUCTION

Lentini, in her summary of Session V of the 9th International Symposium on the Biosafety of Genetically Modified Organisms, raised some important issues for exposure assessments required for the environmental impact analysis of GM crops, and in particular issues surrounding pollen dispersion. Within her summary article there are a few concepts described that require commentary to better understand the value of the various pollen flow modeling approaches presented during the Symposium.

EMPIRICAL MODELING FITTING THE OBSERVED DATA

Empirical models of pollen flow, such as that of Gustafson (2006), are based upon the limited data at hand, and so obviously they must fit the data used in their development when the model and the data are plotted together. Thus, it cannot be construed that the model is tested, nor has it succeeded in any test. The observations noted in Lentini’s summary merely indicate that the model fitting done by Gustafson was carried out correctly.

In order to test any regression-type empirical model, comparison must be made against data collected at times and locations different from those in which the model data were collected. Those further data then can be considered as independent, and so can be compared against the empirical model under the paradigm of hypothetico-deductive scientific methodology based on statistical tests using null and alternative hypotheses. If the statistical test indicates that the model fits the newly acquired and independent data, then the applicability of the model widens to include the conditions under which the new and independent data were collected. Even so, the question of the model’s general applicability remains until enough examples have been found to allow generalization. This is a problem also discussed by Caley (2006) in his presentation during this Symposium.

The generalization of the empirical models rests, therefore, on whether the data used to form that model are representative. For example, Gustafson’s (2006) work on maize is claimed to apply to Europe. He used (nominally)

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Table 1. Time and Location Distribution of Gene Flow datasets used by Gustafson (2006) Class 1 evaluation.

Dataset	Years	# Fields	Locations
Ma et al. (2004)	3 years (2000–2002)	2–3 fields	Agriculture Canada Central Experimental Farm Research Station, Ottawa, Canada
Rosenbaum et al. (2005)	2 years (2001–2002)	2 fields	Monmouth, Illinois, USA
Benetrix and Bloc (2003)	1 year (2002)	2 fields	Gironde and Limagne, France
Halsey et al. (2005)	3 years (2000–2002)	2 fields	California and Washington

Table 2. Time and Location Distribution of Gene Flow datasets used by Gustafson (2006) Class 2 evaluation.

Dataset	Years	# Fields	Locations
Halsey et al. (2005)	3 years (2000–2002)	2 fields	California and Washington
Jones and Brooks (1950)	3 years (1947–1949)	1 field	Oklahoma
Sears and Stanley-Horn (2000)	1 year (2000)	6 fields	Wellington County, Ontario

56 data sets for their determination of border row controls (Class 1), but actually the data were restricted to six distinct locations and only over three years (2000–2002) (Tab. I). The development of their gene flow and isolation distance model (Class 2) is based on data from three studies only, all in North America, from three distinct locations spanning less than 6 years (Tab. II).

For example, Ma et al.'s (2004) data set used in Gustafson's empirical model was collected only in the Ottawa area (at the Agriculture & Agrifood Canada's Central Experimental Farm research station) for 3 years, and so its applicability to other data sets from sites and locations (*i.e.*, Europe) requires verification. Therefore, with such a restricted set of data, 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 under other conditions in North America.

WHAT IS A WORST-CASE OR CONSERVATIVE ESTIMATE OR PREDICTION?

These terms "worst case" and "conservative estimate" have been used widely but without, as far as we are aware, a strict definition. We believe that it is important to define these terms precisely, because the use of worst-case estimation methods underlies many environmental impact assessment (EIA) methods (see for example the Hayes (2006) presentation during this conference).

We consider the terms "worst-case" and "conservative" environmental exposure to be synonymous, and define them as a numerically defined exposure (*e.g.*, pollen grains per cubic meter) that, with a high degree of certainty, equals or exceeds the maximum of all measured data, which is by its very nature always limited in extent. This is a definition that has been adopted by the Province of Ontario, Canada (Ontario Ministry of the Environment, 2005) for its air quality regulatory impact assessment requirements. The definition is useful because it avoids any problems in evaluating the variability of measured data by replacing that variability with a singular value (Abaza et al., 2004). In turn, that also avoids ambiguous statements like "reasonable worst-case" (what is "reasonable" requires definition). Most often, an estimated worst-case exposure value exceeds measured data in-hand by some degree. This adds an element of safety to the impact prediction. However, the degree of exceedance of the estimated worst-case value over whatever measured data are in hand is often not defined or difficult to define. The degree of exceedance is or should be immaterial to regulators, as long as the regulatory standards are met. However, it is important to the regulated community.

From the perspective of the regulated community, the degree of exceedance of the worst-case exposure estimate can only be judged in light of the degree of difficulty to achieve crop isolation based on that worst-case estimate. For example, if a worst-case pollen flow assessment resulted in out-crossing values of 10%, and it were found, by whatever means, that a 500 m wide reproductive isolation distance was required to reduce out-crossing from 10% to 0.9% (the EU standard for GMO acceptability (Official Journal of the European Union, 2003)) then, being a worst-case estimate, the 10% at least equals, or more probably exceeds, the true out-crossing value. In this case the safety factor built into that conservative estimate of 10% is only a problem for producers if implementing the 500 m wide isolation zone is impractical. If it is not a problem, then the control measure is acceptable, and therefore the conservatism of the pollen exposure value is acceptable to the producer. If the control measure is impractical, then the exposure assessment may have to be somehow refined, or some other method must be found to control pollen flow. Refining an impact assessment, making it less conservative and more accurate, in a step-wise manner until compliance is achieved, or an acceptable level of control is introduced, is often termed a "tiered" approach to impact analysis. It is a universal method used in EIAs; see, for example, Hill's (2006), Raybould's (2006) and Andow's (2006) presentations in this Symposium.

As stated above, from a regulator's point of view, the degree of exceedance is or should be immaterial, as long as there is a high degree of confidence that the estimates are worst-case and that the worst-case values do meet the required standards. Should a proponent wish to argue that their particular situation is not worst-case, and be able to back their argument scientifically, regulators would be free to listen objectively to those arguments. In other words, the worst-case should be the regulators' default decision.

It is noteworthy to point out the "reasonable worst-case" model of Gustafson (2006) was exceeded in about 10% of the out-crossing events described and used to construct the model. Should a producer knowingly wish to operate with such an under-estimate of maximal out-crossing events, they may or may not be free to do so. Even so, one would ask whether or not regulators would consider such an exceedance rate acceptable or "reasonable" (however that term is defined).

PROS AND CONS OF EMPIRICAL AND MECHANISTIC MODELS

Lentini points out (and Gustafson (2006) states) that one of the aspects of mechanistic modeling is that there is often a lack of input data and that this makes the models somehow unusable. That is a misconception. A lack of data for certain model inputs is a very common situation in other areas of EIAs where mechanistic models are used, but does not detract from the models' utility. The common practice, short of actually doing extra work to collect those additional data, is to use worst-case values instead of the missing ones. If the resultant worst-case impact estimated using this mechanistic modeling technique is judged to exceed a certain standard, then the proponent may choose to either implement some in-field control, or may wish to refine their impact assessment by finding more accurate input values (*e.g.*, measuring pollen settling velocities (*e.g.*, DiGiovanni et al., 1995), or vegetation filtering efficiencies (Aylor and Ferrandino, 1989), etc). This is all a normal part of conducting EIAs.

However, as indicated earlier, a serious drawback of empirical models is that they are usually based on a data set from specific times, places, and conditions. In particular, the empirical model of Gustafson (2006) is based on a limited data set. The uncertainty over the generality of the empirical approach has been viewed, in other areas of EIAs, as a major drawback and so mechanistic models are often favored as more general, and so are adopted.

The disadvantages of the mechanistic approach, at least for wind pollinated crops, and in the sense explained by DiGiovanni (2006) in this Symposium, are that they tend to be difficult to understand for those who are traditionally trained in agricultural sciences. The development and refinement process for mechanistic models also tends to be longer and require more resources. However, given that the aim of a properly designed mechanistic model is to assure that standards are met with the greatest possible certainty, the drawbacks of the empirical approach outweigh, in our opinion, any difficulties faced in using mechanistic models, at least for wind pollinated crops.

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