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Media Reporting on New GMO Safety Study is Deceptive: Flawed Meta-Analysis Debunked

By GMO Free USA
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A recent meta-analysis titled "Impact of genetically engineered maize on agronomic, environmental and toxicological traits: a meta-analysis of 21 years of field data"(1) by Elisa Pellegrino, et al, concluded that genetically engineered (GE) (also known as genetically modified or GM) corn is substantially equivalent, has higher yields and could be safer than non-GM corn. The review is being touted by mainstream media such as Newsweek Magazine and Forbes as evidence of the safety and benefits of GM corn, with Forbes implying that such claims apply to all GM crops. However, this flawed analysis cannot be used to make such claims, for the following reasons.

Does Not Meet the Criteria for a Meta-Analysis

By definition, a meta-analysis begins with a focused question. Following the development of the focused question a statistical analysis, a pooling and analyzing of data, is completed using all published up-to-date primary research relevant to that focused question. However, sometimes authors claim to have performed a meta-analysis but do not begin with a focused question, arbitrarily selecting primary research that is irrelevant, biased or outdated. In these cases, such a review does not meet the criteria of a meta-analysis.(2) A focused question may not be general, but should be very specific. As an example, the question "Does GM corn grown between 1996 and 2016 have a higher yield compared with its non-GM isoline or near-isoline grown in identical field conditions, throughout its overall cultivation period?," a question addressed in this meta-analysis, is not a focused question. A focused question should take into account information such as geographic location, development of pest resistance, a specific GM event and biased data. An example of a focused relevant question would be, "Does independent evidence demonstrate Mon810 (specific GM corn) increases yield after the development of pest resistance compared with commercially available non-GM corn in identical field conditions in the Midwestern U.S.?" This example looks at a specific GM corn compared only to commercially available corn for a real-world comparison, uses only independent and up-to-date data to control for bias and relevance, and takes into account geographical differences that may alter yield results. Since this meta-analysis does not begin with focused questions, it clearly does not meet the criteria for a meta-analysis.

Small Number of Studies Used Makes Conclusion Weak and Unreliable

Although some articles have claimed that the authors of this meta-analysis have reviewed over 6,000 studies, this is misleading. In total, only 76 of those studies were used to evaluate 34 individual parameters. Only a few studies were cited for each parameter and some were used for multiple parameters. Therefore, this “meta-analysis” uses a very small number of studies, making the results weak and unreliable. The authors admit this, stating, “there is a need for more field research with a wider geographic coverage and having appropriate comparators and field design allowing robust statistical analyses”.(1) A meta-analysis can use as few as two studies. However, depending on the size of those studies, such a small number of studies generally provides weak results. Additionally, even when using two studies those studies must be specific to the focused question of the meta-analysis. For example, combining data from GM Bt1 and Bt2 corn grown in 1994 in parts of the Midwest U.S. and data from GM DKC4442YG and DKC3872YG corn grown in 2013 in Borovce, Slovakia as these authors have done, is not a valid comparison and is not how a meta-analysis is conducted.

Use of Biased Studies Makes Conclusion Unreliable

At least 34% of the data cited in the meta-analysis is attributed to reports that are likely biased due to conflicts of interest (COI). However, the COI percentage may be even higher because some of the studies did not disclose their source of funding. Some of the reports were written by authors that have a COI and either work for a company that produces GM crops or for a lab that partners with companies that make GM crops. Other data comes from reports that were funded by a company that produces GM crops. A recent review of GM corn studies states, “we found that, compared to the absence of COI, the presence of a COI was associated with a 50% higher frequency of outcomes favorable to the interests of the GM crop company.”(3) Therefore it would be less likely, for example, that observations such as non-equivalence and low yields, would be made for studies with a COI. Pooling biased data with unbiased data, as these authors have done, would skew the data in favor of the interests of GM crop companies and make the results unreliable.

Use of Outdated Studies Distorts Data

Nearly all of the GM corn used in the studies these authors selected is created by inserting a gene cassette containing a synthetic combination of DNA including an altered version of a bacterial gene(s) into corn plants. This gene(s) then codes for a protein(s) that is toxic to insects so they die when they attempt to eat the corn. This is commonly referred to as “Bt corn”. However, over time insects have developed resistance to these toxins, allowing them to feed on Bt corn and survive. The authors of the meta-analysis state, “the evolution of resistance in pests and a consequent reduction of the GE crop effectiveness can not be excluded. Actually, resistance and cross-resistance to Bt maize were recently detected”.(1) The authors’ reference to the earliest evidence of resistance was published in 2007.(4) Therefore, all studies published prior to 2007 would be expected to have higher yields, reduced injury and mycotoxins compared to studies from 2007 and after. Combining data from both before and after documented insect resistance distorts the data in favor of higher yield, reduced injury, and reduced mycotoxins, giving the impression that currently grown GM corn is more effective than it really is.

We examined the claims of this meta-analysis as they relate to several of the parameters highlighted in the mainstream media coverage of this study and noted the following problems, which render the conclusions for each parameter weak and/or unreliable:

Grain Yield Analysis Excludes Relevant Studies and is Based Primarily on Biased and Outdated Studies Making Conclusion Unreliable

An examination of the 19 studies included in the Grain Yield Analysis finds 6 studies with a declared COI that should have been excluded. However, the COI percentage may even be higher because some of the studies did not disclose their source of funding. It should be noted that at least some data that appears to fit the criteria of the authors but which observed a similar yield for GM corn compared to its near-isoline was mysteriously excluded from this meta-analysis.(11)

Additionally, when analyzing yield data, a separate calculation should be made based only on the data gathered after the development of insect resistance, during the period from 2007 to 2016. This is necessary to make the analysis relevant to current real world farming conditions. Using this criterion, 13 of the 19 studies included in the grain yield analysis are outdated and should have been excluded, leaving only six relevant studies(5,6,7,8,9,10). Of those six relevant studies, 50% have a declared COI(5,6,9) but the percentage could be higher because some of the studies did not disclose their source of funding. Additionally, one of the three remaining studies is irrelevant because it was conducted in parts of the European Union, Denmark and France(10) where GM corn is not cultivated commercially, making the likelihood of pest resistance low. This leaves only two studies which were relevant to the analysis. Of those two remaining studies, one did not observe a statistically significant grain yield for GM corn compared to non-GM.(7) The other study observed mixed results, with some plantings in some years having a yield increase for some varieties of GM corn and others not.(8) Using only two relevant studies, a very small number of independent studies for a small number of locations, makes the results weak and unreliable. Therefore, using this limited data to conclude that GM corn generally has increased yield for different locations and under different conditions is unscientific.

Damaged Ears Analysis is Based on 7 Total Studies of Which 3 are Biased, 2 are Outdated and Only 2 are Relevant Making Conclusion Weak and Unreliable

Damaged ears refers to a claim that the amount of damage observed in the ears of corn is reduced with GM corn. Damaged ears may be related to the incidence of insect attack. Therefore as insects become resistant to the toxins in GM corn, as occurred in the study published in 2007, it is expected that damaged ears would increase. If data from only 2007 to 2016 are included for injury, only five studies(5,6,8,9,12) are relevant. Of those, 60% have COI.(5,6,9) However, the COI percentage may even be higher because some of the studies did not disclose their source of funding. When those with a COI are eliminated, only two studies are relevant. Using only two relevant studies, a very small number of independent studies for a small number of locations, makes the results weak and unreliable. Therefore using these results to conclude that GM corn has reduced injury in general for different locations and under different conditions is unscientific.

Target Organism Analysis Is Based Entirely on 5 Biased Studies of Which 3 are Outdated Making Conclusion Unreliable

Target organisms are insects which the makers of GM crops aim to kill when the insects attempt to eat the GM corn. Therefore, as insects become resistant to the toxins in GM corn, target organisms would be less likely to die. The authors of this study determined that available data on only "*Diabrotica* spp. [corn rootworm] abundance were sufficient to perform a reliable meta-analysis"(1) and no other target organisms were analyzed. However, field resistance of Diabrotica virgifera virgifera has been documented, appearing around 2011.(13) If studies from only 2011 to 2016, after documented resistance, are included for Diabrotica spp., only two studies are relevant.(14,15) Using only two relevant studies, a very small number of independent studies for a small number of locations, makes the results weak and unreliable. However, all of the five studies the authors used to claim GM corn effectively kills Diabrotica spp. compared to its near-isogenic line included authors who worked for biotech companies Bayer, Monsanto, Syngenta or Dow. Therefore, there is a conflict of interest in 100% of these studies, making the results unreliable(14,15,16,17,18).

Mycotoxin Analysis and Associated Safety Claims Are Based On 9 Total Studies of Which 3 are Biased, 6 Outdated, 2 Irrelevant and Only 1 Relevant Study Making Conclusion Weak and Unreliable

Mycotoxins are toxins that can occur from fungi found on grain. According to the authors, the prevalence of mycotoxins seems to be related to the incidence of insect attack. Therefore, as insects become resistant to the toxins in GM corn, as occurred in the above referenced study published in 2007, it is expected that the mycotoxins on GM corn would increase. If only data following documented insect resistance from 2007 to 2016 is included for mycotoxins, only three studies are relevant (19,20,21). Of those, 33.3% have COI.(19) However, the COI percentage may even be higher because some of the studies did not disclose their source of funding. When those with a COI are eliminated, only two studies are relevant.(20,21) One of these studies was conducted in part of the European Union, France(20), where GM corn is not cultivated commercially making the likelihood of pest resistance low. This leaves only one study published in 2008 that was conducted in an area, Mississippi, that has consistently cultivated GM corn commercially. This single relevant study concluded that there were no statistically significant differences between the levels of mycotoxins in harvested grain and debris from Bt compared to non-GM corn.(21) This is the exact opposite of the conclusion in this meta-analysis and therefore, claims that GM corn is safer than Non-GM are unreliable. In fact, feeding studies using GM corn conducted on mammals found adverse effects, including immune system disturbances (22), male reproductive organ damage (23), disturbances in the functioning of the digestive system (23), hyperlipidemia and higher blood glucose levels (24). Signs of toxicity and/or disturbances in organs or biochemical changes associated with disturbances in the kidneys, liver, spleen, stomach and small intestine have also been observed(23,25-33) in rodents fed GM corn.

Non-Target Organism Analysis Is Based on 32 Total Studies of Which 8 are Biased and Excludes Relevant Studies Making Conclusion Unreliable

Non-Target organisms are organisms which the makers of GM crops do not want to kill when the organisms are exposed to the GM corn or eat other organisms which have been exposed to the GM corn. Of the studies used by the authors for Non-Target Organisms, 8 of 32 or 25% have a declared conflict of interest(17,18, 34-39). However, the COI percentage may even be higher because some of the studies did not disclose their source of funding. Pooling biased data with unbiased data, as these authors have done, would skew the data in favor of the interests of GM crop companies. Had the authors eliminated studies with a conflict of interest it is possible the results may have been changed. However, the authors only used data for certain insects and arachnids, whereas many studies have observed adverse effects from GM corn in several other non-target organisms not included by these authors.(40) It should also be noted that in a survey of entomologists many stated that GM crop makers hindered their research. For example, GM crop producers are able to control which scientists get access to research materials. Some entomologists stated that GM crop producers have "blacklisted" them from conducting any further research on GM crops. One government scientist surveyed stated, "We discovered a non-target effect of Bt pollen on a non-target [insect]. [Insects] fed the pollen experienced nearly 100% mortality. The industry partner suppressed the research and prohibited us from publicizing the results".(41) This suggests that GM crop producers can pick and choose scientists more likely to make statements favorable to the GM crops and that studies observing adverse effects in Non-Target Organisms are being suppressed which further calls into question the accuracy of the results in this meta-analysis.

Substantial Equivalence Analysis is Based Entirely on 3 Biased Studies Done by Monsanto Employees Making Conclusions Unreliable

Substantial equivalence in this study is a claim that GM crops are equivalent to non-GM crops in terms of the levels of proteins, fats and fiber. However, the process of genetic engineering can result in unexpected consequences, potentially causing the plant to produce toxins, create foreign proteins, or other unanticipated results that may damage the plant(42,43). Therefore, claiming substantial equivalence based on the levels of proteins, fats and fiber is unscientific. For example, a Bt crop used in this analysis expresses a Cry protein that is toxic. A GM corn expressing a toxic Cry protein cannot be considered "substantially equivalent" to a non-GM corn that does not express this toxic Cry protein. In the case of the Cry proteins expressed by GM corn, such Cry proteins have been genetically altered prior to insertion and are not the same as Cry proteins found in bacteria found in nature.(44) Therefore, this concept of substantial equivalence has been criticized for being inadequate to assess safety(45,46).

To make the claim of substantial equivalence, the authors cited only three studies that claim GM corn is substantially equivalent to its near-isogenic line (47,48,49). However, all three of those studies involved authors who worked for Monsanto so there is 100% COI, making all of the data unreliable. Additionally, the authors only used data for the levels of certain plant components, whereas several studies have observed other differences in GM corn which demonstrate inequivalence and which were not included by these authors.(50,51)

Use of Isogenic and Near-Isogenic Lines Does Not Resemble Real-World Agriculture and Makes Conclusions Largely Irrelevant

Isogenic and Near-Isogenic lines are nearly identical genetically to the line of corn used to make a GM corn, but before it was genetically engineered. Isogenic and near-isogenic lines are useful to determine differences in the plant caused by the genetic engineering insertion process. However, isogenic lines are often low yielding varieties which are used because they are better able to deal with the stress caused by the genetic engineering process. Once these low yielding plants are genetically engineered they are then backcrossed, breeding the low yielding GM plant with a high yielding non-GM plant through conventional breeding, in order to develop a higher yielding GM plant.(52) Therefore, comparing a GM corn conventionally bred with a high yielding corn, to a low yielding isogenic line that has not been bred with a high yielding corn, stacks the deck in favor of the GM corn. Isogenic and near-isogenic lines are also rarely commercialized and would rarely be available to farmers in a real-life farming situation. Therefore, comparing GM corn to a near-isogenic line for impact on yield, damage, target organisms, mycotoxins or some other criteria, does not represent a real-world scenario. A more relevant comparison would have been to compare high yielding non-GM varieties to GM. For example, there is conventionally bred aflatoxin and fumonisin resistant corn(53). This could be compared to Bt crops for a real-world comparison for yield, mycotoxins and other parameters. However, the authors' selection criteria didn't allow for these types of studies to be included. Therefore, the types of comparisons used by these authors would almost never occur in real-world agriculture.

Conclusion

The Newsweek article by Dana Dovey carrying the headline, "GMO Corn Is Safe and Even Has Health Benefits, Analysis of 6,000 Studies Concludes," is plainly deceptive. And "The Environmentalist Case In Favor Of GMO Food" by Omri Ben-Shahar for Forbes, is a lavish attempt to heap praise on GMO crops and disparage non-GMO foods and the advocates of non-GMO foods. After thoroughly examining this "meta-analysis", it becomes clear that the writers in mainstream media promoting it either lack research skills, have an insincere agenda, or both.

Numerous issues including the use of only a small number of studies, geographically limited data, biased studies, outdated studies and studies which used isogenic and near-isogenic lines that are rarely commercialized, make the data from this 'meta-analysis' and the conclusions drawn, weak and highly unreliable.

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