

GM Crops and the Rat Digestive Tract: Is GM Food Safe for Animals and Humans?

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by I.M. Zdziarski, J.W. Edwards, J.A. Carman, J.I. Haynes

ABSTRACT

The aim of this review is to examine the relationship between genetically modified (GM) crops and health, based on histopathological investigations of the digestive tract in rats. We reviewed published long-term feeding studies of crops containing one or more of three specific traits: herbicide tolerance via the EPSPS gene and insect resistance via cry1Ab or cry3Bb1 genes. These genes are commonly found in commercialised GM crops.

Our search found 21 studies for nine (19%) out of the 47 crops approved for human and/or animal consumption. We could find no studies on the other 38 (81%) approved crops.

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Fourteen out of the 21 studies (67%) were general health assessments of the GM crop on rat health. Most of these studies (76%) were performed after the crop had been approved for human and/or animal consumption, with half of these being published at least nine years after approval. Our review also discovered an inconsistency in methodology and a lack of defined criteria for outcomes that would be considered toxicologically or pathologically significant.

In addition, there was a lack of transparency in the methods and results, which made comparisons between the studies difficult. The evidence reviewed here demonstrates an incomplete picture regarding the toxicity (and safety) of GM products consumed by humans and animals. Therefore, each GM product should be assessed on merit, with appropriate studies performed to indicate the level of safety associated with them. Detailed guidelines should be developed which will allow for the generation of comparable and reproducible studies. This will establish a foundation for evidence-based guidelines, to better determine if GM food is safe for human and animal consumption.

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excerpts

Have enough studies been conducted to adequately state that GM crops are safe for human and animal consumption?

Genetically modified crops have been approved for human and animal consumption for nearly 20 years (Clive and Krattiger, 1996) yet the debate about their safety continues. Fifty-three crops are known to possess at least one of the genes investigated in this review (herbicide tolerance via the *EPSPS* gene and insect resistance via the *cry1Ab* or *cry3Bb1* genes). Forty-seven of these crops have been approved for animal and/or human consumption, yet published toxicity studies could be found for only nine of these crops (19%) (Table 1). Of greater concern is that for eight of these crops, publications appeared after the crop had been approved for human and/or animal consumption. We understand that other studies may exist that are commercial in confidence, but these studies are not accessible to the scientific community. Other than the few studies mentioned in the EFSA reports, where histopathological results were not reported, our review of the published literature wasn't able to identify or locate any reported safety evaluations performed on rats on these eight crops prior to their approval. Our literature review also did not identify or locate published reports on rats for the remaining 38 crops.

The present review limited the search to only include feeding studies done on rats so that the results may be comparable. It is possible that more studies may be found if the search were to be extended to other animals. However, based on what has been found for rat studies, it is unlikely that any additional studies would involve a thorough safety investigation and a detailed report of all of the 47 approved GM crops possessing one or more of the three traits. Moreover, the rat model is the accepted OECD standard for toxicological studies of this type.

Whilst the safety of a GM crop is primarily and sometimes solely evaluated by government food regulators using the test for substantial equivalence, this is likely to be inadequate to fully assess the safety of the crop for reasons stated above. Animal feeding studies provide a more thorough method of investigating the unintended effects of the GM process or the unintended effects of ingesting GM crop components. Animal feeding studies can identify target organs as well as predict the chronic toxic effect of an ingested compound (<u>OECD</u>, 2008)

Conclusions

The evidence reviewed here demonstrates an incomplete picture regarding the toxicity (and safety) of GM crops consumed by humans and animals. The majority of studies reviewed lacked a unified approach and transparency in their methodology and results, making it impossible to properly review or repeat these studies. Furthermore, such lack of detail makes it difficult to generate evidence-based guidelines to aid in the delivery of an optimum safety assessment process for GM crops for animal and human consumption.

When considering how a better risk assessment could be done, it is important to consider systems established for other novel substances that may generate unintended effects. For example, the registration of pharmaceutical products requires an examination of both benefits and risks associated with their use and a complete assessment of those benefits and risks to establish whether the products are appropriate for general use at a range of doses. We argue that each GM crop should be assessed using similar methods, where a GM crop is tested in the form and at the rates it will be consumed by animals and people. Whilst this provides for an effective general approach, there are additional issues for assessing GM crops that need to be taken into account. For example, the process of developing GM crops may generate unintended effects. Furthermore, the plant developed is a novel entity with genes, regulatory sequences and proteins that interact in complex ways. Therefore, the resultant plant should be assessed as a whole so that any pleiotropic effects can also be assessed. As a result, long-term animal feeding studies should be included in risk assessments of GM crops, together with thorough histopathological investigations using a variety of methods to better detect subtle changes or the beginning or presence of pathologies. Such robust and detailed studies will then make it possible to put evidence-based guidelines in place, which will substantially help to determine the safety of GM crops for human and animal consumption

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