

DISCUSSION

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No scientific consensus on GMO safety

Angelika Hilbeck^{1,2*}, Rosa Binimelis^{1,3}, Nicolas Defarge^{1,4,5}, Ricarda Steinbrecher^{1,6}, András Székács^{1,7}, Fern Wickson^{1,3}, Michael Antoniou⁸, Philip L Bereano⁹, Ethel Ann Clark¹⁰, Michael Hansen¹¹, Eva Novotny¹², Jack Heinemann¹³, Hartmut Meyer¹, Vandana Shiva¹⁴ and Brian Wynne¹⁵

Abstract

A broad community of independent scientific researchers and scholars challenges recent claims of a consensus over the safety of genetically modified organisms (GMOs). In the following joint statement, the claimed consensus is shown to be an artificial construct that has been falsely perpetuated through diverse fora. Irrespective of contradictory evidence in the refereed literature, as documented below, the claim that there is now a consensus on the safety of GMOs continues to be widely and often uncritically aired. For decades, the safety of GMOs has been a hotly controversial topic that has been much debated around the world. Published results are contradictory, in part due to the range of different research methods employed, an inadequacy of available procedures, and differences in the analysis and interpretation of data. Such a lack of consensus on safety is also evidenced by the agreement of policymakers from over 160 countries - in the UN's Cartagena Biosafety Protocol and the Guidelines of the *Codex Alimentarius* - to authorize careful case-by-case assessment of each GMO by national authorities to determine whether the particular construct satisfies the national criteria for 'safe'. Rigorous assessment of GMO safety has been hampered by the lack of funding independent of proprietary interests. Research for the public good has been further constrained by property rights issues, and by denial of access to research material for researchers unwilling to sign contractual agreements with the developers, which confer unacceptable control over publication to the proprietary interests.

The joint statement developed and signed by over 300 independent researchers, and reproduced and published below, does not assert that GMOs are unsafe or safe. Rather, the statement concludes that the scarcity and contradictory nature of the scientific evidence published to date prevents conclusive claims of safety, or of lack of safety, of GMOs. Claims of consensus on the safety of GMOs are not supported by an objective analysis of the refereed literature.

Background

Over recent years, a number of scientific research articles have been published that report disturbing results from genetically modified organism (GMO) feeding experiments with different mammals (e.g. rats [1], pigs [2]). In addition to the usual fierce responses, these have elicited a concerted effort by genetically modified (GM) seed developers and some scientists, commentators, and journalists to construct claims that there is a 'scientific consensus' on GMO safety [3-5] and that the debate on this topic is 'over' [6].

These claims led a broader independent community of scientists and researchers to come together as they felt compelled to develop a document that offered a balanced account of the current state of dissent in this field, based on published evidence in the scientific literature, for both the interested public and the wider science community. The statement that was developed was then opened up for endorsement from scientists around the world with relevant expertise and capacities to conclude on the current state of consensus/dissent and debate regarding the published evidence on the safety of GMOs.

This statement clearly demonstrates that the claimed consensus on GMO safety does not exist outside of the above depicted internal circle of stakeholders. The health, environment, and agriculture authorities of most nations recognize publicly that no blanket statement about the

* Correspondence: angelika.hilbeck@ensser.org

¹European Network of Scientists for Social and Environmental Responsibility (ENSSER Board/Secretariat), Marienstrasse 19/20, 10117 Berlin, Germany

²Institute of Integrative Biology, Swiss Federal Institute of Technology Zurich, Universitätsstrasse 16, 8092 Zurich, Switzerland

Full list of author information is available at the end of the article

safety of all GMOs is possible and that they must be assessed on a 'case-by-case' basis. Moreover, the claim that it does exist - which continues to be pushed in the above listed circles - is misleading and misrepresents or outright ignores the currently available scientific evidence and the broad diversity of scientific opinions among scientists on this issue. The claim further encourages a climate of complacency that could lead to a lack of regulatory and scientific rigour and appropriate caution, potentially endangering the health of humans, animals, and the environment.

Science and society do not proceed on the basis of a constructed consensus, as current knowledge is always open to well-founded challenge and disagreement. We endorse the need for further independent scientific inquiry and informed public discussion on GM product safety.

Some of our objections to the claim of a scientific consensus are listed in the following discussion. The original version endorsed by 300 scientists worldwide can be found at the website of the European Network of Scientists for Social and Environmental Responsibility [7].

Discussion

1 *There is no consensus on GM food safety*

Regarding the safety of GM crops and foods for human and animal health, a comprehensive review of animal feeding studies of GM crops found 'An equilibrium in the number [of] research groups suggesting, on the basis of their studies, that a number of varieties of GM products (mainly maize and soybeans) are as safe and nutritious as the respective conventional non-GM plant, and those raising still serious concerns'. The review also found that most studies concluding that GM foods were as safe and nutritious as those obtained by conventional breeding were 'performed by biotechnology companies or associates, which are also responsible [for] commercializing these GM plants' [8].

A separate review of animal feeding studies that is often cited as showing that GM foods are safe included studies that found significant differences in the GM-fed animals. While the review authors dismissed these findings as not biologically significant [9], the interpretation of these differences is the subject of continuing scientific debate [8,10-12] and no consensus exists on the topic.

Rigorous studies investigating the safety of GM crops and foods would normally involve, *inter alia*, animal feeding studies in which one group of animals is fed GM food and another group is fed an equivalent non-GM diet. Independent studies of this type are rare, but when such studies have been performed, some have revealed toxic effects or signs of toxicity in the GM-fed animals

[2,8,11-13]. The concerns raised by these studies have not been followed up by targeted research that could confirm or refute the initial findings.

The lack of scientific consensus on the safety of GM foods and crops is underlined by the recent research calls of the European Union and the French government to investigate the long-term health impacts of GM food consumption in the light of uncertainties raised by animal feeding studies [14,15]. These official calls imply recognition of the inadequacy of the relevant existing scientific research protocols. They call into question the claim that existing research can be deemed conclusive and the scientific debate on biosafety closed.

2 *There are no epidemiological studies investigating potential effects of GM food consumption on human health*

It is often claimed that 'trillions of GM meals' have been eaten in the US with no ill effects. However, no epidemiological studies in human populations have been carried out to establish whether there are any health effects associated with GM food consumption. As GM foods and other products are not monitored or labelled after release in North America, a major producer and consumer of GM crops, it is scientifically impossible to trace, let alone study, patterns of consumption and their impacts. Therefore, claims that GM foods are safe for human health based on the experience of North American populations have no scientific basis.

3 *Claims that scientific and governmental bodies endorse GMO safety are exaggerated or inaccurate*

Claims that there is a consensus among scientific and governmental bodies that GM foods are safe, or that they are no more risky than non-GM foods [16,17], are false. For instance, an expert panel of the Royal Society of Canada issued a report that was highly critical of the regulatory system for GM foods and crops in that country. The report declared that it is 'scientifically unjustifiable' to presume that GM foods are safe without rigorous scientific testing and that the 'default prediction' for every GM food should be that the introduction of a new gene will cause 'unanticipated changes' in the expression of other genes, the pattern of proteins produced, and/or metabolic activities. Possible outcomes of these changes identified in the report included the presence of new or unexpected allergens [18].

A report by the British Medical Association concluded that with regard to the long-term effects of GM foods on human health and the environment, 'many unanswered questions remain' and that 'safety concerns cannot, as yet, be dismissed completely on the basis of

information currently available'. The report called for more research, especially on potential impacts on human health and the environment [19].

Moreover, the positions taken by other organizations have frequently been highly qualified, acknowledging data gaps and potential risks, as well as potential benefits, of GM technology. For example, a statement by the American Medical Association's Council on Science and Public Health acknowledged 'a small potential for adverse events ... due mainly to horizontal gene transfer, allergenicity, and toxicity' and recommended that the current voluntary notification procedure practised in the US prior to market release of GM crops be made mandatory [20]. It should be noted that even a 'small potential for adverse events' may turn out to be significant, given the widespread exposure of human and animal populations to GM crops.

A statement by the board of directors of the American Association for the Advancement of Science (AAAS) affirming the safety of GM crops and opposing labelling [21] cannot be assumed to represent the view of AAAS members as a whole and was challenged in an open letter by a group of 21 scientists, including many long-standing members of the AAAS [22]. This episode underlined the lack of consensus among scientists about GMO safety.

4 *EU research project does not provide reliable evidence of GM food safety*

An EU research project [23] has been cited internationally as providing evidence for GM crop and food safety. However, the report based on this project, 'A Decade of EU-Funded GMO Research', presents no data that could provide such evidence from long-term feeding studies in animals.

Indeed, the project was not designed to test the safety of any single GM food but to focus on 'the development of safety assessment approaches' [24]. Only five published animal feeding studies are referenced in the SAFOTEST section of the report, which is dedicated to GM food safety [25]. None of these studies tested a commercialized GM food; none tested the GM food for long-term effects beyond the subchronic period of 90 days; all found differences in the GM-fed animals, which in some cases were statistically significant; and none concluded on the safety of the GM food tested, let alone on the safety of GM foods in general. Therefore, the EU research project provides no evidence for sweeping claims about the safety of any single GM food or of GM crops in general.

5 *List of several hundred studies does not show GM food safety*

A frequently cited claim published on an Internet website that several hundred studies 'document the general

safety and nutritional wholesomeness of GM foods and feeds' [26] is misleading. Examination of the studies listed reveals that many do not provide evidence of GM food safety and, in fact, some provide evidence of a lack of safety. For example:

- Many of the studies are not toxicological animal feeding studies of the type that can provide useful information about health effects of GM food consumption. The list includes animal production studies that examine parameters of interest to the food and agriculture industry, such as milk yield and weight gain [27,28]; studies on environmental effects of GM crops; and analytical studies of the composition or genetic makeup of the crop.
- Among the animal feeding studies and reviews of such studies in the list, a substantial number found toxic effects and signs of toxicity in GM-fed animals compared with controls [29-34]. Concerns raised by these studies have not been satisfactorily addressed and the claim that the body of research shows a consensus over the safety of GM crops and foods is false and irresponsible.
- Many of the studies were conducted over short periods compared with the animal's total lifespan and cannot detect long-term health effects [35,36].

We conclude that these studies, taken as a whole, are misrepresented on the Internet website as they do not 'document the general safety and nutritional wholesomeness of GM foods and feeds'. Rather, some of the studies give serious cause for concern and should be followed up by more detailed investigations over an extended period of time.

6 *There is no consensus on the environmental risks of GM crops*

Environmental risks posed by GM crops include the effects of insecticidal Bt (a bacterial toxin from *Bacillus thuringiensis* engineered into crops) crops on non-target organisms and the effects of the herbicides used in tandem with herbicide-tolerant GM crops.

As with GM food safety, no scientific consensus exists regarding the environmental risks of GM crops. A review of environmental risk assessment approaches for GM crops identified shortcomings in the procedures used and found 'no consensus' globally on the methodologies that should be applied, let alone on standardized testing procedures [37]. Some reviews of the published data on Bt crops have found that they can have adverse effects on non-target and beneficial organisms [38-41] - effects that are widely neglected in regulatory assessments and by some scientific commentators. Resistance

to Bt toxins has emerged in target pests [42], and problems with secondary (non-target) pests have been noted, for example, in Bt cotton in China [43,44].

Herbicide-tolerant GM crops have proved equally controversial. Some reviews and individual studies have associated them with increased herbicide use [45,46], the rapid spread of herbicide-resistant weeds [47], and adverse health effects in human and animal populations exposed to Roundup, the herbicide used on the majority of GM crops [48-50].

As with GM food safety, disagreement among scientists on the environmental risks of GM crops may be correlated with funding sources. A peer-reviewed survey of the views of 62 life scientists on the environmental risks of GM crops found that funding and disciplinary training had a significant effect on attitudes. Scientists with industry funding and/or those trained in molecular biology were very likely to have a positive attitude to GM crops and to hold that they do not represent any unique risks, while publicly-funded scientists working independently of GM crop developer companies and/or those trained in ecology were more likely to hold a 'moderately negative' attitude to GM crop safety and to emphasize the uncertainty and ignorance involved. The review authors concluded 'The strong effects of training and funding might justify certain institutional changes concerning how we organize science and how we make public decisions when new technologies are to be evaluated' [51].

7 International agreements show widespread recognition of risks posed by GM foods and crops

The Cartagena Protocol on Biosafety was negotiated over many years and implemented in 2003. The Cartagena Protocol is an international agreement ratified by 166 governments worldwide that seeks to protect biological diversity from the risks posed by GM technology. It embodies the Precautionary Principle in that it allows signatory states to take precautionary measures to protect themselves against threats of damage from GM crops and foods, even in case of a lack of scientific certainty [52].

Another international body, the UN's Codex Alimentarius, worked with scientific experts for 7 years to develop international guidelines for the assessment of GM foods and crops because of concerns about the risks they pose. These guidelines were adopted by the Codex Alimentarius Commission, of which over 160 nations are members, including major GM crop producers such as the United States [53].

The Cartagena Protocol and Codex share a precautionary approach to GM crops and foods, in that they agree that genetic engineering differs from conventional breeding and that safety assessments should be required

before GM organisms are used in food or released into the environment.

These agreements would never have been negotiated, and the implementation processes elaborating how such safety assessments should be conducted would not currently be happening, without widespread international recognition of the risks posed by GM crops and foods and the unresolved state of existing scientific understanding. Concerns about risks are well founded, as has been demonstrated by studies on some GM crops and foods that have shown adverse effects on animal health and non-target organisms, indicated above. Many of these studies have, in fact, fed into the negotiation and/or implementation processes of the Cartagena Protocol and the Codex. We support the application of the Precautionary Principle with regard to the release and transboundary movement of GM crops and foods.

Conclusions

In the scope of this document, we can only highlight a few examples to illustrate that the totality of scientific research outcomes in the field of GM crop safety is nuanced; complex; often contradictory or inconclusive; confounded by researchers' choices, assumptions, and funding sources; and, in general, has raised more questions than it has currently answered.

Whether to continue and expand the introduction of GM crops and foods into the human food and animal feed supply, and whether the identified risks are acceptable or not, are decisions that involve socioeconomic considerations beyond the scope of a narrow scientific debate and the currently unresolved biosafety research agendas. These decisions must therefore involve the broader society. They should, however, be supported by strong scientific evidence on the long-term safety of GM crops and foods for human and animal health and the environment, obtained in a manner that is honest, ethical, rigorous, independent, transparent, and sufficiently diversified to compensate for bias.

Decisions on the future of our food and agriculture should not be based on misleading and misrepresentative claims by an internal circle of likeminded stakeholders that a 'scientific consensus' exists on GMO safety.

This document was subsequently opened for endorsement by scientists from around the world in their personal (rather than institutional) capacities reflecting their personal views and based on their personal expertise. There is no suggestion that the views expressed in this statement represent the views or position of any institution or organization with which the individuals are affiliated. Qualifying criteria for signing the statement were deliberately selected to include scientists, physicians, social scientists, academics, and specialists in legal aspects and risk assessment of GM crops and foods. Scientist and

academic signatories were requested to have qualifications from accredited institutions at the level of PhD or equivalent. Legal experts were requested to have at least a JD or equivalent. By December 2013, more than 300 people who met the strict qualification requirements had signed the statement. The statement was widely taken up in the media and reported in numerous outlets and evidence provided therein continues to be cited widely. In a time when there is major pressure on the science community from corporate and political interests, it is of utmost importance that scientists working for the public interest take a stand against attempts to reduce and compromise the rigour of examination of new applications in favor of rapid commercialization of new and emerging technologies that are expected to generate profit and economic growth. The document continues to be open for signature on the website of the initiating scientific organization ENSSER (European Network of Scientists for Social and Environmental Responsibility) at www.ensser.org.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

All authors contributed equally to the writing of the document. All authors read and approved the final manuscript.

Authors' information

EAC is retired.

Author details

¹European Network of Scientists for Social and Environmental Responsibility (ENSSER Board/Secretariat), Marienstrasse 19/20, 10117 Berlin, Germany. ²Institute of Integrative Biology, Swiss Federal Institute of Technology Zurich, Universitätsstrasse 16, 8092 Zurich, Switzerland. ³GenØk Centre for Biosafety, Forskningsparken, PB 6418, 9294 Tromsø, Norway. ⁴Comité de Recherche et d'Information Indépendantes sur le génie Génétique CRIIGEN, 40 rue Monceau, 75008 Paris, France. ⁵University of Caen, Institute of Biology IBFA and Network on Risks, Quality and Sustainable Environment MRSH, Esplanade de la Paix, 14032 Caen, France. ⁶EcoNexus, Oxford OX4 9BS, UK. ⁷Central Environmental and Food Science Research Institute, POB 393, H-1537 Budapest, Hungary. ⁸Department of Medical and Molecular Genetics, Faculty of Life Sciences and Medicine, King's College London, Guy's Hospital, London SE1 9RT, UK. ⁹Technology and Public Policy, University of Washington, Seattle, Washington 98195, USA. ¹⁰Plant Agriculture, University of Guelph, K0K 3 K0 Warkworth, Ontario, Canada. ¹¹Consumers Union, 101 Truman Avenue, Yonkers, NY 10703, USA. ¹²Clare Hall, University of Cambridge, Herschel Road, Cambridge CB3 9AL, UK. ¹³Centre for Integrated Research in Biosafety, School of Biological Sciences, University of Canterbury, Christchurch, New Zealand. ¹⁴Navdanya Hauz Khas, New Delhi 110016, India. ¹⁵Centre for the Study of Environmental Change, CSEC, Lancaster University, Lancaster, UK.

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