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No scientific consensus on GMO safety

As scientists, physicians, academics, and experts from disciplines relevant to the scientific, legal, social and safety assessment aspects of genetically modified organisms (GMOs),¹ we strongly reject claims by GM seed developers and some scientists, commentators, and journalists that there is a “scientific consensus” on GMO safety^{2 3 4} and that the debate on this topic is “over”.⁵

We feel compelled to issue this statement because the claimed consensus on GMO safety does not exist. The claim that it does exist is misleading and misrepresents the currently available scientific evidence and the broad diversity of opinion among scientists on this issue. Moreover, the claim 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 and urge GM proponents to do the same.

Some of our objections to the claim of scientific consensus are listed below.

1. There is no consensus on GM food safety

¹ In the US, the term “genetically engineered” is often used in place of “genetically modified”. We have used “genetically modified” because this is the terminology consistently used by many authorities internationally, including the Food and Agriculture Organization of the United Nations; the World Health Organization; Codex Alimentarius; European and Indian legislation; peer-reviewed studies by industry and independent scientists; and the international media. It is also consistent with the Cartagena Protocol’s term “living modified organism”.

² Frewin, G. (2013). The new “is GM food safe?” meme. Axis Mundi, 18 July. <http://www.axismundionline.com/blog/the-new-is-gm-food-safe-meme/>; Wikipedia (2013). Genetically modified food controversies. http://en.wikipedia.org/wiki/Genetically_modified_food_controversies

³ Mark Lynas (2013). GMO pigs study – more junk science. Marklynas.org, 12 June. <http://www.marklynas.org/2013/06/gmo-pigs-study-more-junk-science/>

⁴ Keith Kloor (2013). Greens on the run in debate over genetically modified food. Bloomberg, 7 January. <http://www.bloomberg.com/news/2013-01-07/green-activist-reverses-stance-on-genetically-modified-food.html>

⁵ White, M. (2013). The scientific debate about GM foods is over: They’re safe. Pacific Standard magazine, 24 Sept. <http://www.psmag.com/health/scientific-debate-gm-foods-theyre-safe-66711/>

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”.⁶

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,⁷ the interpretation of these differences is the subject of continuing scientific debate^{8 9 10 11} and no consensus exists on the topic.

Rigorous studies investigating the safety of GM crops and foods would normally involve 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.^{12 13 14 15 16 17} 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

⁶ Domingo, J. L. and J. G. Bordonaba (2011). A literature review on the safety assessment of genetically modified plants. *Environ Int* 37: 734–742.

⁷ Snell, C., et al. (2012). Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: A literature review. *Food and Chemical Toxicology* 50(3–4): 1134-1148.

⁸ Séralini, G. E., et al. (2011). Genetically modified crops safety assessments: Present limits and possible improvements. *Environmental Sciences Europe* 23(10).

⁹ Dona, A. and I. S. Arvanitoyannis (2009). Health risks of genetically modified foods. *Crit Rev Food Sci Nutr* 49(2): 164–175.

¹⁰ Domingo, J. L. and J. G. Bordonaba (2011). *Ibid.*

¹¹ Diels, J., et al. (2011). Association of financial or professional conflict of interest to research outcomes on health risks or nutritional assessment studies of genetically modified products. *Food Policy* 36: 197–203.

¹² Domingo, J. L. and J. G. Bordonaba (2011). *Ibid.*

¹³ Diels, J., et al. (2011). *Ibid.*

¹⁴ Dona, A. and I. S. Arvanitoyannis (2009). *Ibid.*

¹⁵ Séralini, G. E., et al. (2012). Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. *Food and Chemical Toxicology* 50(11): 4221-4231.

¹⁶ Séralini, G. E., et al. (2013). Answers to critics: Why there is a long term toxicity due to NK603 Roundup-tolerant genetically modified maize and to a Roundup herbicide. *Food and Chemical Toxicology* 53: 461-468.

¹⁷ Carman, J. A., et al. (2013). A long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet. *Journal of Organic Systems* 8(1): 38–54.

government to investigate the long-term health impacts of GM food consumption in the light of uncertainties raised by animal feeding studies.^{18 19} 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 are not labelled 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,^{20 21} 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.²²

¹⁸ EU Food Policy (2012). Commission and EFSA agree need for two-year GMO feeding studies. 17 December.

¹⁹ French Ministry of Ecology, Sustainable Development and Energy (2013). Programme National de Recherche: Risques environnementaux et sanitaires liés aux OGM (Risk'OGM). 12 July. http://www.developpement-durable.gouv.fr/IMG/pdf/APR_Risk_OGM_rel_pbch_pbj_rs2.pdf

²⁰ Wikipedia (2013). Genetically modified food controversies.

http://en.wikipedia.org/wiki/Genetically_modified_food_controversies

²¹ G. Masip (2013). Opinion: Don't fear GM crops, Europe! The Scientist, May 28. <http://www.the-scientist.com/?articles.view/articleNo/35578/title/Opinion--Don-t-Fear-GM-Crops--Europe/>

²² Royal Society of Canada (2001). Elements of precaution: Recommendations for the regulation of Food Biotechnology in Canada; An Expert Panel Report on the Future of Food Biotechnology. January. http://www.rsc.ca/files/publications/expert_panels/foodbiotechnology/GMreportEN.pdf

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.²³

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.²⁴ 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 labelling²⁵ 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.²⁶ 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 project²⁷ 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”.²⁸ Only five published animal feeding studies are referenced in the SAFOTEST section of the

²³ British Medical Association Board of Science and Education (2004). Genetically modified food and health: A second interim statement. March. <http://bit.ly/19QAHSI>

²⁴ American Medical Association House of Delegates (2012). Labeling of bioengineered foods. Council on Science and Public Health Report 2. <http://www.ama-assn.org/resources/doc/csaph/a12-csaph2-bioengineeredfoods.pdf>

²⁵ AAAS (2012). Statement by the AAAS Board of Directors on labeling of genetically modified foods. 20 October. http://www.aaas.org/news/releases/2012/media/AAAS_GM_statement.pdf

²⁶ Hunt, P., et al. (2012). Yes: Food labels would let consumers make informed choices. Environmental Health News. <http://www.environmentalhealthnews.org/ehs/news/2012/yes-labels-on-gm-foods>

²⁷ European Commission (2010). A decade of EU-funded GMO research (2001–2010).

²⁸ European Commission (2010): 128.

report, which is dedicated to GM food safety.²⁹ None of these studies tested a commercialised 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”³⁰ 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;^{31 32} 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.^{33 34 35 36 37 38} Concerns raised by these studies have not been satisfactorily addressed and the claim that the body

²⁹ European Commission (2010): 157.

³⁰ Tribe, D. (undated). 600+ published safety assessments. GMOPundit blog. <http://gmopundit.blogspot.co.uk/p/450-published-safety-assessments.html>

³¹ Brouk, M., et al. (2008). Performance of lactating dairy cows fed corn as whole plant silage and grain produced from a genetically modified event DAS-59122-7 or a nontransgenic, near isoline control. *J Anim. Sci. (Sectional Meeting Abstracts)* 86(e-Suppl. 3):89 Abstract 276.

³² Calsamiglia, S., et al. (2007). Effects of corn silage derived from a genetically modified variety containing two transgenes on feed intake, milk production, and composition, and the absence of detectable transgenic deoxyribonucleic acid in milk in Holstein dairy cows. *J Dairy Sci* 90: 4718-4723.

³³ de Vendômois, J.S., et al. (2010). A comparison of the effects of three GM corn varieties on mammalian health. *Int J Biol Sci.* ;5(7):706-26.

³⁴ Ewen, S.W.B. and A. Pusztai (1999). Effect of diets containing genetically modified potatoes expressing *Galanthus nivalis* lectin on rat small intestine. *Lancet* 354:1353-1354.

³⁵ Fares, N.H., and A. K. El-Sayed (1998). Fine structural changes in the ileum of mice fed on delta-endotoxin-treated potatoes and transgenic potatoes. *Nat Toxins.* 6:219-33.

³⁶ Kilic, A. and M. T. Akay (2008). A three generation study with genetically modified Bt corn in rats: Biochemical and histopathological investigation. *Food Chem Toxicol* 46(3): 1164–1170.

³⁷ Malatesta, M., et al. (2002). Ultrastructural morphometrical and immunocytochemical analyses of hepatocyte nuclei from mice fed on genetically modified soybean. *Cell Structure and Function* 27:173-180.

³⁸ Malatesta, M., et al. (2003). Fine structural analyses of pancreatic acinar cell nuclei from mice fed on genetically modified soybean. *European Journal of Histochemistry* 47:385-388

- 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.^{39 40}

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 Bt insecticidal crops on non-target organisms and 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.⁴¹

Some reviews of the published data on Bt crops have found that they can have adverse effects on non-target and beneficial organisms^{42 43 44 45} – effects that are widely neglected in regulatory assessments and by some scientific commentators. Resistance to Bt toxins has emerged in target pests,⁴⁶ and problems with secondary (non-target) pests have been noted, for example, in Bt

³⁹ Hammond, B., et al. (2004). Results of a 13 week safety assurance study with rats fed grain from glyphosate tolerant corn. *Food Chem Toxicol* 42(6): 1003-1014.

⁴⁰ Hammond, B. G., et al. (2006). Results of a 90-day safety assurance study with rats fed grain from corn borer-protected corn. *Food Chem Toxicol* 44(7): 1092-1099.

⁴¹ Hilbeck, A., et al. (2011). Environmental risk assessment of genetically modified plants - concepts and controversies. *Environmental Sciences Europe* 23(13).

⁴² Hilbeck, A. and J. E. U. Schmidt (2006). Another view on Bt proteins – How specific are they and what else might they do? *Biopesti Int* 2(1): 1–50.

⁴³ Székács, A. and B. Darvas (2012). Comparative aspects of Cry toxin usage in insect control. *Advanced Technologies for Managing Insect Pests*. I. Ishaaya, S. R. Palli and A. R. Horowitz. Dordrecht, Netherlands, Springer: 195–230.

⁴⁴ Marvier, M., et al. (2007). A meta-analysis of effects of Bt cotton and maize on nontarget invertebrates. *Science* 316(5830): 1475-1477.

⁴⁵ Lang, A. and E. Vojtech (2006). The effects of pollen consumption of transgenic Bt maize on the common swallowtail, *Papilio machaon* L. (Lepidoptera, Papilionidae). *Basic and Applied Ecology* 7: 296–306.

⁴⁶ Gassmann, A. J., et al. (2011). Field-evolved resistance to Bt maize by Western corn rootworm. *PLoS ONE* 6(7): e22629.

cotton in China.^{47 48}

Herbicide-tolerant GM crops have proved equally controversial. Some reviews and individual studies have associated them with increased herbicide use,^{49 50} the rapid spread of herbicide-resistant weeds,⁵¹ and adverse health effects in human and animal populations exposed to Roundup, the herbicide used on the majority of GM crops.^{52 53 54}

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.”⁵⁵

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

⁴⁷ Zhao, J. H., et al. (2010). Benefits of Bt cotton counterbalanced by secondary pests? Perceptions of ecological change in China. *Environ Monit Assess* 173(1-4): 985-994.

⁴⁸ Lu, Y., et al. (2010). Mirid bug outbreaks in multiple crops correlated with wide-scale adoption of Bt cotton in China. *Science* 328(5982): 1151-1154.

⁴⁹ Benbrook, C. (2012). Impacts of genetically engineered crops on pesticide use in the US – The first sixteen years. *Environmental Sciences Europe* 24(24).

⁵⁰ Heinemann, J. A., et al. (2013). Sustainability and innovation in staple crop production in the US Midwest. *International Journal of Agricultural Sustainability*: 1–18.

⁵¹ Powles, S. B. (2008). Evolved glyphosate-resistant weeds around the world: Lessons to be learnt. *Pest Manag Sci* 64: 360–365.

⁵² Székács, A. and B. Darvas (2012). Forty years with glyphosate. *Herbicides - Properties, Synthesis and Control of Weeds*. M. N. Hasaneen, InTech.

⁵³ Benedetti, D., et al. (2013). Genetic damage in soybean workers exposed to pesticides: evaluation with the comet and buccal micronucleus cytome assays. *Mutat Res* 752(1-2): 28-33.

⁵⁴ Lopez, S. L., et al. (2012). Pesticides used in South American GMO-based agriculture: A review of their effects on humans and animal models. *Advances in Molecular Toxicology*. J. C. Fishbein and J. M. Heilman. New York, Elsevier. 6: 41–75.

⁵⁵ Kvakkestad, V., et al. (2007). Scientists’ perspectives on the deliberate release of GM crops. *Environmental Values* 16(1): 79–104.

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.⁵⁶

Another international body, the UN's Codex Alimentarius, worked with scientific experts for seven 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.⁵⁷

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 Codex. We support the application of the Precautionary Principle with regard to the release and transboundary movement of GM crops and foods.

Conclusion

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

⁵⁶ Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to the Convention on Biological Diversity. <http://bch.cbd.int/protocol/text/>

⁵⁷ Codex Alimentarius (2009). Foods derived from modern biotechnology. 2d ed. World Health Organization/Food and Agriculture Organization of the United Nations. ftp://ftp.fao.org/codex/Publications/Booklets/Biotech/Biotech_2009e.pdf

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 that a “scientific consensus” exists on GMO safety.

The document was first signed by 92 persons.

The document is now open for further signatures and all agreeing with the content are invited to sign the statement at: www.ensser.org