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Dear Sirs

**The Safe Food Institute
Submission
Gene Technology Act Review 2011**

Slater & Gordon have recently been retained by The Safe Food Institute (SFI) to review the release and regulation of genetically modified organisms within Australia. The SFI has been established to conduct and support research into food safety. This submission puts before the review a body of material the SFI submits must be considered. The Gene Technology Act (GT Act), the role of federal and state governments and their authorities in regulating the release of genetically modified organisms (GMOs) will be a central focus of that review.

Given the extremely short review period allocated by the Gene Technology Ministerial Council (GTMC), this submission is not a comprehensive review. Specifically this submission seeks to place before the GTMC a body of scientific evidence of harm arising from the release and or use of GMOs which illustrates the concerns which the SFI considers this review must take into account in considering the future operation of the GT Act if the object of the GT Act is to be achieved.

We note that the object of the GT Act is defined below:

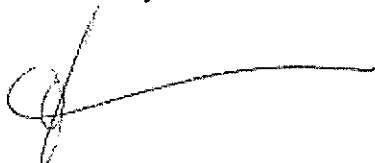
The object of the Act is to protect the health and safety of people and the environment from risks posed by, or as a result of, gene technology by identifying those risks and managing them by regulating certain dealings with genetically modified organisms (GMOs). The Act establishes a regulatory framework through which its object is to be achieved. This framework provides for a precautionary approach and an efficient and effective system for the application of gene technologies that is intended to operate in conjunction with other Australian Government and State and Territory regulatory schemes relevant to GMOs and GM products.

The SFI submits that the GT Act has comprehensively failed in its object to protect public health and safety, the environment, and our economy from harm caused by the licensed release of GMOs. The GT Act also fails to establish an effective regulatory framework or take a precautionary approach to achieve its object.

Instead, the GT Act enables regulators to issue licenses to GMO proponents who are not required to prove their products are safe. The onus of proof of danger or harm is left to the Australian public who are the unwilling and uninformed experimental subjects exposed to the often unlabelled consumption of GMOs. Even when this evidence of harm is provided, the regulators (and therefore the GT Act) fail to operate to protect against further harm.

It is the view of the SFI that the growing body of concerns and scientific evidence justifies the recommendation of a comprehensive and independent legal or parliamentary review of the operation and effectiveness of the GT Act. The SFI submits, pending the outcome of such an enquiry, that the GTMC should impose a moratorium on any further approvals under the GT Act and conduct an urgent safety review of all current dealings with GMOs licensed under the GT Act to date.

Yours faithfully

A handwritten signature in black ink, consisting of a stylized initial 'M' followed by a long horizontal stroke.

Mark Walter
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Summary of evidence provided by The Safe Food Institute

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Appendix A: 2 Key Scientific Papers On Gmo Safety Issues

These are two recent papers that strike to the core of safety concerns regarding the release of GMO's. Both of these are attached in PDF form for the GTMC to consider.

- (1) Aris, A and Leblanc, S. (2011) "Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada." *Reproductive Toxicology*, 2011 May; 31(4):528-33. Epub 2011 Feb 18.
- (2) Antoniou, M et al. (2011) " Roundup and birth defects: Is the public being kept in the dark?". Earth Open Source.

Appendix B: 70 Key Scientific Papers On Gmo Safety Issues

We have not attached these papers rather given the references so GTMC can access them.

- (1) Agodi, A. et al. (2006) "Detection of genetically modified DNA sequences in milk from The Italian market". *International Journal of Hygiene and Environmental Health*, 209, 81-88.
- (2) Benachour N, Sipahutar H, Moslemi S. et al. "Time- and dose- dependent effects of roundup on human embryonic and placental cells". *Arch Environ Contam Toxicol*. 2007;53:126-133
- (3) Benachour, N. and Seralini, G-E. 2008, "Glyphosate Formulations Induce Apoptosis and Necrosis in Human Umbilical, Embryonic, and Placental Cells", *Chemical Research in Toxicology*, DOI: 10.1021/ tx800218n. Publication Date (Web): December 23, 2008
- (4) Bernstein, I.L., Bernstein, J.A., Miller, M., Tierzieva, S., Bernstein, D.I., Lummus, Z., Selgrade, M.K., Doerfler, D.L. and Seligy, V.L. (1999). "Immune responses in farm workers after exposure to *Bacillus thuringiensis* pesticides", *Environmental Health Perspectives* 107, 575-582
- (5) Chowdhury, EH., et al (2003) "Detection of corn intrinsic and recombinant DNA fragments and Cry1Ab protein in the gastrointestinal contents of pigs fed genetically modified corn Bt11". *Journal of Animal Science* 81, 2546-2551.
- (6) Cisterna B, Flach F, Vecchio L, Barabino SM, Battistelli S, Martin TE, Malatesta M, Biggiogera M. 2008, "Can a genetically- modified organism-containing diet influence embryo development? A preliminary study on pre-implantation mouse embryos". *Eur J Histochem*. 2008 Oct-Dec; 52(4):263-7.
- (7) Duggan et al., 2003, "Fate of genetically modified maize DNA in the oral cavity and rumen of sheep", *British Journal of Nutrition*, 2003,
- (8) Dutton, A., H. Klein, J. Romeis, and F. Bigler, 2002, "Uptake of Bt-toxin by herbivores feeding on transgenic maize and consequences for the predator *Chrysoperia carnea*," *Ecological Entomology* 27 (2002): 441–7
- (9) Ermakova, I.V. 2006, "Genetically modified soy leads to the decrease of weight and high mortality of rat pups of the first generation. Preliminary studies," *Ecosinform* 1 (2006): 4–9.
- (10) Ermakova, I.V. 2009. "Influence of soy with gene EPSPS CP4 on the physiological state and reproductive functions of rats in the first two generations," *Russian Academy of Natural Sciences, "Modern problems of science and education" № 5, 2009. UDC: 612.82, 57.02*
- (11) Ewen S.W. and Pusztai A., 1999 "Effect of diets containing genetically modified potatoes expressing *Galanthus nivalis* lectin on rat small intestine", *Lancet*, vol. 354, pp. 1353–1354.
- (12) Fares NH, El-Sayed AK. 1998 "Fine structural changes in the ileum of mice fed on delta-endotoxin-treated potatoes and transgenic potatoes". *Nat Toxins*. 6: 219-33.
- (13) Finamore A, Roselli M, Britti S, Monastra G, Ambra R, Turrini A and Mengheri E. (2008). "Intestinal and peripheral immune response to MON810 maize ingestion in weaning and old mice". *J Agric Food Chem*, 16 November 2008
- (14) Fu, T.J. et al. (2002) "Digestibility of food allergens and nonallergenic proteins in simulated gastric fluid and simulated intestinal fluid – A comparative study". *Journal of Agricultural Food Chemistry*, 50, 7154-7160.
- (15) Guerrero, GG. W.M. Russel and L. Moreno-Fierros, 2007: "Analysis of the cellular immune response induced by *Bacillus thuringiensis* Cry1Ac toxins in mice: Effect of the hydrophobic motif from diphtheria toxin". *Molecular Immunology* 44, 1209-1217 (2007)).
- (16) Kilić, 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.
- (17) Kroghsbo S, Madsen C, Poulsen M, Schrøder M, Kvist PH, Taylor M, Gatehouse A, Shu Q, Knudsen I. "Immunotoxicological studies of genetically modified rice expressing PHA-E lectin or Bt toxin in Wistar rats". *Toxicology*. 2008 Mar 12;245(1-2):24-3
- (18) Lutz, B. et al. (2005) "Degradation of Cry1Ab protein from genetically modified maize in the bovine gastrointestinal tract". *Journal of Agricultural Food Chemistry*, Published on Web, 10.1021/ jf0492222x, American Chemical Society.

- (19) Malatesta, M., F Perdoni, G Santin, S Battistelli, S Muller, M Biggiogera (2008). "Hepatoma tissue culture (HTC) cells as a model for investigating the effects of low concentrations of herbicide on cell structure and function". *Toxicol In Vitro*. 2008 Sep 18; : 18835430
- (20) Malatesta M, Caporaloni C, Gavaudon S. et al. 2002, "Ultrastructural morphometrical and immunocytochemical analyses of hepatocyte nuclei from mice fed on genetically modified soybean". *Cell Struct Funct*. 2002; 27:173-180
- (21) Malatesta M, Biggiogera M, Manuali E. et al. 2003, "Fine structural analyses of pancreatic acinar cell nuclei from mice fed on genetically modified soybean". *Eur J Histochem*. 2003; 47:385-388
- (22) Manuela Malatesta, Federica Boraldi, Giulia Annovi, Beatrice Baldelli, Serafina Battistelli, Marco Biggiogera, Daniela Quaglinò. (2008) "A long-term study on female mice fed on a genetically modified soybean: effects on liver ageing". *Histochem Cell Biol*. 2008 Jul 22; : 18648843
- (23) Malatesta, M. et al. (2002b) "Ultrastructural analysis of pancreatic acinar cells from mice fed on genetically modified soybean". *Journal of Anatomy*, 201, 409-446.
- (24) Mazza R, Soave M, Morlacchini M, Piva G, Marocco A.(2005) "Assessing the transfer of genetically modified DNA from feed to animal tissues". *Transgenic Res*. 2005 Oct;14(5):775-84.
- (25) Netherwood, T. (2004) "Assessing the survival of transgenic plant DNA in the human gastrointestinal tract". *Nature Biotechnology*, 22, 204-209.
- (26) Nordgård L , Grønsberg IM, Hegge B, Fenton K, Nielsen KM, Bardocz S, Pusztai A and Traavik T. 2009. An examination of the fate of feed-derived DNA in various tissue samples of actively growing rats, pregnant rats and their foeti. Submitted
- (27) Prescott V.E., Campbell P.M., Moore A., Mattes J., Rothenberg M.E., Foster P.S., Higgins T.J. and Hogan S.P. 2005, "Transgenic expression of bean alpha-amylase inhibitor in peas results in altered structure and immunogenicity", *J Agric Food Chem.*, vol 53, pp. 9023– 9030, ., 2005
- (28) Pryme, IF and Rolf Lembcke, 2003, "In Vivo Studies on Possible Health Consequences of Genetically Modified Food and Feed—with Particular Regard to Ingredients Consisting of Genetically Modified Plant Materials," *Nutrition and Health* 17(2003): 1–8.
- (29) Séralini GE, de Vendômois JS, Cellier D, Sultan C, Buiatti M, Gallagher L, Antoniou M, Dronamraju KR. "How Subchronic and Chronic Health Effects can be Neglected for GMOs, Pesticides or Chemicals". *Int J Biol Sci* 2009; 5:438-443.
- (30) Seralini GE, Cellier D, Spiroux de Vendomois J. 2007, "New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity". *Arch Environ Contam Toxicol*. 2007;52:596-602
- (31) Sharma R, Alexander TW, John SJ, Forster RJ, McAllister TA. 2004, "Relative stability of transgene DNA fragments from GM rapeseed in mixed ruminal cultures". *Br J Nutr*. 2004 May;91(5):673-81.
- (32) Sharma R, Damgaard D, Alexander TW, Dugan ME, Aalhus JL, Stanford K, McAllister TA. (2006) "Detection of transgenic and endogenous plant DNA in digesta and tissues of sheep and pigs fed Roundup Ready canola meal". *J Agric Food Chem*. 2006 Mar 8;54(5): 1699-709.
- (33) Tayabali AF and Seligy VL. 2000, "Human cell exposure assays of *Bacillus thuringiensis* commercial insecticides: production of *Bacillus cereus*-like cytolytic effects from outgrowth of spores". *Environ Health Perspect* 108: 919-930, (2000).
- (34) Trabalza-Marinucci M, Brandi G, Rondini C, Avellini L, Giammarini C, Costarelli S, Acuti G, Orlandi C, Filippini G, Chiaradia E, Malatesta M, Crotti S, Antonini C, Amagliani G, Manuali E, Mastrogiacomo AR, Moscati L, Haouet MN, Gaiti A, Magnani M (2008). "A three year longitudinal study on the effects of a diet containing genetically modified Bt176 maize on the health status and performance on sheep". *Livestock Sci* 113:178–190
- (35) Tudisco R, Lombardi P, Bovera F, d'Angelo D, Cutrignelli MI, Mastellone V, Terzi V, Avallone L, Infascelli F (2006) "Genetically modified soya bean in rabbit feeding: detection of DNA fragments and evaluation of metabolic effects by enzymatic analysis." *Anim Sci* 82:193–199
- (36) R.I. Vázquez, L. Moreno-Fierros, L. Neri-Bazán, G.A. De la Riva and R. López-Revilla: "Bacillus thuringiensis Cry1Ac protoxin is a potent systemic and mucosal adjuvant". *Scandinavian Journal of Immunology* 49, 578-584 (1999);
- (37) Vazquez Padron, R.I., Moreno Fierros, L., Neri Bazan, L., De la Riva, G.A. and Lopez Revilla, R. "Intragastric and intraperitoneal administration of Cry1Ac protoxin from

- Bacillus thuringiensis induces systemic and mucosal antibody responses in mice". *Life Sciences* 64, 1897-1912. (1999);
- (38) Vazquez-Padron, R.I., Moreno-Fierros, L., Neri-Bazan, L., Martinez-Gil, A.F., de la Riva, G.A. and Lopez-Revilla, R.(2000) "Characterization of the mucosal and systemic immune response induced by Cry1Ac protein from *Bacillus thuringiensis* HD 73 in mice". *Brazilian Journal of Medical and Biological Research* 33, 147-155 (2000);
- (39) Vazquez Padron, R.I., Gonzalez Cabrera, J., Garcia Tovar, C., Neri Bazan, L., Lopez Revilla, R., Hernandez, M., Morena Fierros, L. and De la Riva, G.A. (2000) "Cry1Ac protoxin from *Bacillus thuringiensis* sp. kurstaki HD73 binds to surface proteins in the mouse small intestine". *Biochemical and Biophysical Research Communications* 271, 54-58 (2000)).
- (40) Vazquez-Padron, R.I. Et al. (2000) "Characterization of the mucosal and systemic immune response induced by Cry1Ac protein from *Bacillus thuringiensis* HD 73 in mice". *Brazilian Journal of Medical and Biological Research* 33, 147-155.
- (41) Vecchio L, Cisterna B, Malatesta M, Martin TE, Biggiogera M (2004) "Ultrastructural analysis of testes from mice fed on genetically modified soybean". *Eur J Histochem* 48:449-453
- (42) Velimirov A, Binter C and Zentek J. (2008) "Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies in mice". Report, Forschungsberichte der Sektion IV, Band 3. Institut für Ernährung, and Forschungsinstitut für biologischen Landbau, Vienna, Austria, November 2008.
- (43) Vendômois, JS, François Roullier, Dominique Cellier and Gilles- Eric Séralini. 2009, "A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health" . *International Journal of Biological Sciences* 2009; 5(7):706-726
- (44) Yum, HY. (2005) "Genetically modified and wild soybeans: An immunologic comparison". *Allergy and Asthma Proceedings*, 26, 210-216.
-
- (45) Carman J. 2004, "Is GM Food Safe to Eat?" In: Hindmarsh R, Lawrence G, editors. *Recoding Nature Critical Perspectives on Genetic Engineering*. Sydney: UNSW Press; 2004. p. 82-93.
- (46) Cummins J and Ho MW. 2006. "GM crops for health?" *ISIS Report*, 24 September 2006, submitted to Codex Alimentarius public consultation
- (47) Domingo, J.L. (2000) Health risks of genetically modified foods: many opinions but few data. *Science* 288, 1748-1749.
- (48) Domingo J.L. 2007, "Toxicity studies of genetically modified plants: a review of the published literature". *Crit Rev Food Sci Nutr*. 2007;47(8):721-33
- (49) Dona, A. and Arvanitoyannis, IS, 2009, "Health Risks of Genetically Modified Foods", *Critical Reviews in Food Science and Nutrition*, 49:164-175 (2009)2
- (50) Ermakova, I.V. 2007, "Experimental Evidence of GMO Hazards," Presentation at Scientists for a GM Free Europe, EU Parliament, Brussels, June 12, 2007
- (51) Freese, W. "GE crop impacts health evaluation: a critique of US regulation of GE crops..... a case study of BT corn." FoE, US publication.
- (52) Freese, W. 2001. "The StarLink Affair, Submission by Friends of the Earth to the FIFRA Scientific Advisory Panel considering Assessment of Additional Scientific Information Concerning StarLink Corn," July 17-19, 2001.
- (53) Doug Gurian-Sherman, "Holes in the Biotech Safety Net, FDA Policy Does Not Assure the Safety of Genetically Engineered Foods," Center for Science in the Public Interest, http://www.cspinet.org/new/pdf/fda_report_final.pdf
- (54) Heinemann, J.A. 2009 "Report on animals exposed to GM ingredients in animal feed" (July 2009) Gendora / Commerce Commission of New Zealand
- (55) Ho, Mae-wan (2002) THE BEST KEPT SECRET OF GM CROPS, Witness Statement to ACRE (Open hearing on the T25 GM maize risk assessment.)
- (56) Ho MW and Cummins J. 2004, "GM food and feed not fit for man or beast". *ISIS Report*, ISP Briefing to UK Parliament, 7 May 2004.
- (57) Ho, Mae-wan and Cummins, Joe, 2009, "New evidence links CaMV 35S promoter to HIV transcription," *Microbial Ecology in Health and Disease*. 2009; 21: 172-174
- (58) Ho, Mae-Wan, Cummins, Joe and Saunders, Peter , 2007, 'GM food nightmare unfolding in the regulatory sham', *Microbial Ecology in Health and Disease*, 1 - 12 (2007)
- (59) Ho MW and Steinbrecher RA. 1998. "Fatal flaws in food safety assessment: critique of the joint FAO/WHO Biotechnology and Food Safety Report. *Environmental & Nutritional Interactions* 1998, 2, 51-84.

- (60) Marshall, A. 2007. GM soybeans and health safety—a controversy reexamined. *Nature Biotechnology* 25, 981 - 987 (2007) doi:10.1038/nbt0907-981
- (61) Maessen, GDF. 1997. Genomic stability and stability of expression in genetically modified plants. *Acta Botanica Neerlandica* 46(1) pp 3-24
- (62) Novotny E. 2004. "Animals avoid GM food, for good reasons". *Science in Society* 21, 9-11, 2004.
- (63) Pusztai, A and S.Bardocz, 2006: "GMO in animal nutrition: potential benefits and risks". In: "Biology of Nutrition in Growing Animals" (ed. Mosenthin, R. Zentek, J. and Zebrowska, T.) 2006 Elsevier Limited, pp. 513-540).
- (64) Pusztai, A. et al. (2003) Genetically Modified Foods: Potential Human Health Effects. In: *Food Safety: Contaminants and Toxins* (ed. JPF D'Mello) pp. 347-372. CAB International, Wallingford Oxon, UK.
- (65) Quist, D., and Traavik, T., 2006. Safety assessment of GMOs: Human risks and research needs. *Proceedings of the International workshop on biosafety: Environmental Impacts and Safety Regulation of Genetically Modified Organisms*, Nanjing, China, China Environmental Press, p. 11-21.
- (66) Seralini, G-E 2005. "Genome fluidity and health risks for GMOs." *Epigenetics, Transgenic Plants and Risk Assessment, Conference Proceedings*, Frankfurt, 2005.)
- (67) Snow, A. et al. (2005) "Genetically engineered organisms and the environment: Current status and recommendations". *Ecological Applications*, 15, 377-404.
- (68) Traavik T. 2008. "GMOs and their unmodified counterparts: substantially equivalent or different?" Pp 32-34, in: Breckling B, Reuter H and Verhoeven R: *Implications of GM-Crop Cultivation at Large Spatial Scales. Theorie in der Ökologie* vol. 14, Peter Lang, Frankfurt, 2008 (ISBN 978-3-631-58939-7)
- (69) Traavik, T. and Jack Heinemann, (2006) "Genetic Engineering and Omitted Health Research: Still No Answers to Ageing Questions", 2006. Genok -- Centre for Biosafety
- (70) Wilson, AK, Latham, JR and Steinbrecher, RA, 2006. "Transformation-induced mutations in transgenic plants: Analysis and biosafety implications." *Biotechnology and Genetic Engineering Reviews* – Vol. 23, December 2006, pp.209-237
- (71) Wolfanberger, LL. & Phifer, PR. (2000) The ecological risks and benefits of genetically engineered plants. *Science*, 290, 2088-2093.

NOTE:

The above papers relate only to the direct and indirect effects of the consumption of GM food and feed – i.e. evidence of (1) GM plant toxicity (this would include all animal feeding, immunotoxicity, inhalation etc trials) and (2) evidence of potential harm from the indirect effects of GM plants through inseparable or unavoidable production methods (e.g. the effects of added Roundup residues which are unique to Roundup Ready plants or possibly other HT plants). Some papers discuss the survival of DNA from GM plants in the mammal digestive system, since there are obvious health implications.

We do not include papers which show environmental damage, relating to GM plant toxicity to animals in the food web (these may result in environmental harm or increase the evidence of potential human toxicities) and relating to potential harm to the food web from the indirect effects of GM plants through inseparable or unavoidable production methods (this could include the rise in glyphosate resistant weeds that also increase the chance of their toxins contaminating human food supplies).

The papers towards the end of the list are recommended reviews which summarise earlier published raw data -- and look for cause and effect relationships -- but which do not necessarily report new experimental data.

Appendix C: Gmo Industry Blocks Research

Pro-GM journal Nature Biotech journal in October 2009, criticized the GM industry for blocking research:

“Are the crop industry’s strong-arm tactics and close-fisted attitude to sharing seeds holding back independent research and undermining public acceptance of transgenic crops?”

Pro-GM journal Scientific American in August 2009, also criticized the GM industry for blocking research:

“Scientists must ask corporations for permission before publishing independent research on genetically modified crops. That restriction must end”

To access GM seeds and crops for research is a legal and practical challenge, which has blocked research of evidence of harm.

Appendix D: GMO Industry Attacks On Scientists

Árpád Pusztai (8 September 1930) is a Hungarian-born biochemist and nutritionist who spent 36 years at the Rowett Research Institute in Aberdeen, Scotland. He is a world expert on plant lectins, authoring 270 papers and three books on the subject. In 1998 Pusztai publicly announced that the results of his research showed feeding genetically modified potatoes to rats had negative effects on their stomach lining and immune system. This led to Pusztai being suspended and his annual contract was not renewed. The resulting controversy became known as the Pusztai affair.

Nature journal in September 2009, criticized GM scientists abuse: i.e.

"Papers suggesting that biotech crops might harm the environment attract a hail of abuse from other scientists. Emily Waltz asks if the critics fight fair."

"These strikes are launched from within the scientific community and can sometimes be emotional and personal; heated rhetoric that dismisses papers and can even, as in Rosi-Marshall's case, accuse scientists of misconduct. "The response we got - it went through your jugular," says Rosi-Marshall.

Amnesty reports, in August 2010, the violent harassment of Professor Andres Carrasco for his 2009 research, on the negative effects of glyphosate, on embryos (glyphosate causes birth defects and is used in 70% of GM crops); ie,

"(Prof Carrasco's) ...talk was suspended because the delegation was attacked by a group of around 100 people who threatened them and beat them. One person has since suffered from lower body paralysis after being hit on his spine, and another is undergoing neurological examinations after receiving blows to the head. The former provincial Sub-Secretary of Human Rights, Marcelo Salgado, was struck in the face and left unconscious. Dr Carrasco and his colleague shut themselves in a car, and were surrounded by people making violent threats and beating the car for two hours. Members of the community were injured and a journalist's camera equipment was damaged."

Appendix E: GMO Industry & Government Ignore Expert Report

The 2008 IAASTD report, an intergovernmental process supported by over 400 experts under the co-sponsorship of the FAO, GEF, UNDP, UNEP, UNESCO, the World Bank and WHO, stated: "the way the world grows its food will have to change radically to better serve the poor and hungry if the world is to cope with growing population and climate change while avoiding social breakdown and environmental collapse.";

"Assessment of modern biotechnology is lagging behind development; information can be anecdotal and contradictory, and uncertainty on benefits and harms is unavoidable. There is a wide range of perspectives on the environmental, human health and economic risks and benefits of modern biotechnology, many of which are as yet unknown." (SR Summary, p. 14)

"The application of modern biotechnology outside containment, such as the use of GM crops is much more contentious. For example, data based on some years and some GM crops indicate highly variable 10-33% yield gains in some places and yield declines in others." (SR Summary, p. 14)

Professor Jack Heinemann co-authored the biotechnology section of the 2009 IAASTD Synthesis Report. In 2004, Monsanto submitted its GM high lysine maize to FSANZ (Food Standards Australia and New Zealand ~ national food safety regulator). In December 2007 FSANZ approved GM high lysine maize as safe for human consumption.

Heinemann's group made multiple submissions to FSANZ which were taken up by regulators in EU member states. Among the issues raised were risks of cancer, diabetes and Alzheimer's disease.

The EU regulators' submissions to EFSA (European Food Safety Authority) were often based on Heinemann's work. The outcome caused EFSA to ask for some of the same safety tests that Heinemann had attempted to get FSANZ to require. EFSA's request for safety information resulted in Monsanto withdrawing a GM product from EFSA consideration, rather than supply the results of these tests.

FSANZ maintains there is no safety issue with LY038, and that it was withdrawn from Europe purely for commercial reasons.

Heinemann comments:

"Monsanto estimated the street value of LY038 was going to be US\$1 billion a year. Do we really believe that a market of US\$1bn a year is too small for Monsanto? I don't. The European Food Safety Authority requested more safety data from Monsanto."

At the end of April 2009, two letters were sent to EFSA by Monsanto's European subsidiary company Renessen, withdrawing applications originally submitted in 2005 and requesting the return of all dossier material (varietal characterization, experimental protocols, and test results) which was submitted with the applications for cultivation, animal feed and human food. EFSA acceded to this request, making it impossible for any future independent researchers to analyse the Monsanto / Renessen data.

Dr Brian John of GM Free Cymru has dealt extensively on this issue with EFSA, and summarizes Heinemann submission to FSANZ / EFSA as follows:

The Monsanto dossiers included rigged research and false assumptions in the reported experiments; a failure to offer any test results based on cooked or processed corn [the way humans, but not animals, eat it]; a failure to test the whole GM plant in feeding trials; confusing and contradictory characterizations of the GM varieties and proteins; a fraudulent mixing of GM strains during trials; a pooling of crop data so as to mask undesirable effects in experiments; feeding trials too short to reveal true physiological changes in animal tissues; and the choice of an irrelevant, unrelated corn variety as the control group for comparison with the GM lines, with the clear intention of hiding potentially serious differences in composition or side effects on animals.

The Codex guidelines for the testing of GM crops were thus comprehensively broken by Monsanto's subsidiary Renessen, and were not enforced by the regulators in the USA, Canada,

Australia and New Zealand. All in all, this amounted to blatant scientific fraud by the applicants, and a cynical failure to enforce the rules, and to protect the public, by the regulators.

Appendix F: Government Sell Out Of Science To Gmo Commerce

Dr Don Lotter comments on the failure of science, in the International Journal of Sociology of Agriculture and Food (IJSAF):

At the core of this failure appears to be the restructuring of research university science programs in the past 25 years from a non-proprietary 'public goods' approach to one based on dependence on private industry. Additional ramifications of this shift that have been factors in the transgenics issue are:

tolerance by the scientific community of bias against (and mistreatment of) non-compliant scientists, whose work results in negative findings for transgenics, including editorial decisions by peer-reviewed journals, as well as tolerance of

- biotechnology industry manipulation of the information environment;
- monopolization of the make-up of expert scientific bodies on transgenics by pro-
- industry scientists with vested interests in transgenics;
- deficient scientific protocols, bias, and possible fraud in industry-sponsored and industry-conducted safety testing of transgenic foods; and
- increasing politically and commercially driven manipulation of science within federal regulatory bodies such as the FDA.

Landes Bioscience in March/April 2010, published an article titled Conducting public-sector research on commercialized transgenic seed, criticizing the GM industry:

"(GM) ...industry partners may unduly influence the way research is designed and disseminated."

<http://www.newscientist.com/article/mg20427335.400-stop-selling-out-science-to-commerce.html?full=true&print=true>

Stop selling out science to commerce

04 November 2009 by [Stuart Parkinson](#) and [Chris Langley](#)
Magazine issue [2733](#).

DO COMMERCIAL pressures have a negative impact on science? This debate has been raging for so long that it usually raises little more than a shrug of indifference.

That is no longer a defensible response. A new report from our organisation, Scientists for Global Responsibility (SGR), exposes problems so serious that we can no longer afford to be indifferent to them.

The report looks at the impact of five commercial sectors on science and technology over the past 20 years. The damaging influence of two of these, pharmaceuticals and tobacco, has been noted before. But we also looked at the oil and gas, defence and biotech sectors, which have been subjected to less scrutiny.

We found a wide range of disturbing commercial influences on science, and evidence that similar problems are occurring across academic disciplines.

Over the past two decades, government policy in the US, UK and elsewhere has fundamentally altered the academic landscape in a drive for profit. Universities have been pushed to adopt a much more commercial mindset, from taking out patents to prioritising research that promises short-term economic gains. The rapid spread of partnerships between businesses and universities has led to some disciplines becoming so intertwined with industry that few academics are able to retain their independence.

Chemical engineering and geology are strongly linked to oil companies, for example, and it is hard to find an engineering department in the UK which does not receive funding from the arms industry. And many life sciences departments have extensive links with the biotechnology and pharmaceutical industries.

This creates enormous potential for conflicts of interest. The problem has long been recognised in medical research, and journals are starting to crack down on it, but in other disciplines the problems are rarely even discussed, let alone acted upon.

Such problems are a major concern because they can undermine the quality and reliability of research. This is perhaps best illustrated by "sponsorship bias", where research generates results that suit the funder (The Journal of the American Medical Association, vol 290, p 921). Another well-documented problem is the failure to report results unfavourable to the funder.

Research is also undermined by misleading messages put out by industry-funded lobby groups. Again, these tactics are well known from the tobacco and oil industries, with their deliberate questioning of health research and sponsorship of climate sceptics. Less attention has been given to the funding of some patient groups by pharmaceutical companies and the (sometimes covert) use of PR companies by the biotechnology industry in the debate over genetically modified crops. This does not bode well for public discussions on the risks of synthetic biology.

Another cornerstone of science that is being eroded is the freedom to set the public research agenda so that it serves the public interest. Governments are increasingly focused on delivering competitiveness, and business interests are able to exert pressure on funding bodies through representatives on their boards. As a result, environmental and social problems and "blue-sky" research commonly lose out to short-term commercial gain.

For example, genetics now dominates agricultural science, not least because genetic technologies are highly patentable. This not only dominates privately funded research, but also steers publicly funded research away from work that takes a different approach or explores low-tech solutions.

As a result, "low-input" agriculture, which requires minimal use of chemical fertilisers and pesticides and is cheaper and more useful to poorer farmers, is largely overlooked. Similarly, research on how to improve food distribution receives inadequate support.

Another example is research on security issues, which is overwhelmingly focused on new military technology. Research into understanding the roots of conflict, or to support negotiation and reconciliation programmes, receives a tiny fraction of the tens of billions of dollars spent globally on developing military hardware. And most of that is public money.

Put bluntly, much publicly funded science is no longer being done in the public interest. Despite this, policy-makers are complacent and argue that any damaging effects of commercial influence are minor.

In contrast, many scientists are noticing the effects and becoming discomfited by them. Some are starting to speak out. For example, staff at the Open University in the UK are pushing for new ethical standards for business partnerships following the university's involvement in a major military contract.

However, these campaigns are few and far between. There is a strong incentive for scientists not to make a fuss if their department receives industry funds. This is strengthened by contractual requirements for secrecy that often come with industry partnerships.

To defend independent science, reform is needed, from the level of government policy down to that of the research study. To this end, SGR is making recommendations. These include: the open publication of all funding arrangements between academia and business; ethical standards for business-university partnerships; proper handling of conflicts of interests by journals; more involvement of the public in setting research priorities; and a change in government policies which prioritise research with short-term commercial priorities above all else.

Scientists must now voice their concerns publicly in order that policy-makers hear them. They could do worse than follow the example set by campaigners at the Open University.

Stuart Parkinson and Chris Langley are authors of the SGR report Science and the Corporate Agenda, which can be downloaded from sgr.org.uk