

Press Notice from GM-Free Cymru
Immediate Release
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MONSANTO PULLS GM CORN AMID SERIOUS FOOD SAFETY CONCERNS

Applicant's dossiers contained wide-ranging fraudulent research

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For the first time, a GM multinational has pulled two GM corn varieties from the regulatory and assessment process at the eleventh hour (1), after planning for a future income of several billion dollars per year from global sales (2). Monsanto has abandoned its ambitious plans for a so-called "second generation GM crop" rather than accede to a request from European regulators for additional research and safety data (3).

Under conditions of great secrecy, Monsanto has informed EFSA that it no longer wishes to pursue its application for approval of GM maize LY038 and the stacked variety LY038 x MON810. Both of these varieties were designed to accelerate the growth rate of animals. Two letters were sent to EFSA from the Monsanto subsidiary company Renessen at the end of April this year confirming the withdrawal of its applications originally submitted in 2005 and 2006. The letters cite "decreased commercial value worldwide" and state that the high-lysene varieties "will no longer be a part of the Renessen business strategy in the near future." (4) There has been no announcement of these decisions on the Monsanto web site, and there are no mentions on EFSA or European Commission web sites either. In other words, there is a conspiracy of silence involving both the applicants and the regulators.

The two letters sent to EFSA in April requested 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 (4). EFSA acceded to this request, making it impossible for any future independent researchers to analyse the Monsanto / Renessen data. That in itself is profoundly disturbing.

Scientists who have followed these two applications are quite convinced that the "decisions to withdraw" have nothing to do with commercial

considerations and everything to do with food safety. In other words, the varieties are too dangerous to be allowed onto the open market -- although they would certainly have been approved by EFSA and most other European regulatory authorities had it not been for the diligence of independent scientists in New Zealand who subjected the application dossiers to very close scrutiny (5). In the absence of such scrutiny in the United States, the varieties were approved in 2005 for cultivation, animal feed and human food use on the other side of the Atlantic (6). Consents for food and feed use were also given in Japan, Canada, the Philippines, and South Korea. In 2007 Food Standards Australia and New Zealand (FSANZ) approved LY038 for food and feed use in spite of strenuous objections from the Green Party and scientists at Canterbury University's Centre for Integrated Research in Biosafety (INBI) who warned that the new corn was not safe for humans when cooked (7). They also expressed concerns about unpredictable health effects, increased levels of toxins in high-lysene corn, and possible allergies and links to cancer.

It does not appear that the varieties have been grown or "commercialized" anywhere in the world (8), although test plantings probably occurred in the United States.

"Blatant scientific fraud by the applicants"

While INBI's detailed and devastating analysis of the applicant's supporting dossiers was dismissed out of hand by FSANZ, EFSA was forced to take it seriously because of concerns from a large number of European countries including Finland and Malta. The scientific bases of those concerns were highlighted by Jeffrey Smith in his book "Genetic Roulette" and by Prof Jack Heinemann in his book "Hope not Hype" (9). 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; 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(10). 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 (11). 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.

During the assessments of these two varieties in Europe, many countries used the INBI peer review of the applicant's dossiers to underpin their concerns, and these widely-expressed concerns forced EFSA to ask the applicants for additional studies and for a clarification of their experimental data (12). EFSA also asked -- for the first time -- for adherence to the Codex rules relating to GM and comparator studies. In the knowledge that their dossiers were now being subjected to an unprecedented level of scrutiny, Monsanto / Renessen simply decided that they would not cooperate in this process for fear of what might emerge. So they wrote to EFSA in April (4) to indicate that they were abandoning all plans for the cultivation and commercialization of the two GM crops.

"EFSA has been unfit for purpose"

Commenting for GM-Free Cymru, Dr Brian John said: "This is the first time, to our knowledge, that EFSA has sought to enforce the Codex rules relating to the use of isolines in the testing of GM crops, and the first time that it has expressed profound dissatisfaction about the content of an applicant's dossiers. It is also the first time that a GM multinational has withdrawn a GM product (or two products) at the eleventh hour. It was insane in the first place to seek to pass GM maize crops containing Bt toxins and "growth enhancers" straight into the human food chain (13). In addition, EFSA and the other regulators have been quite irresponsible in the past in assuming that "stacked" events, hybridized from two GM lines, are harmless if the applicant says so, and if the separate lines have been independently approved. That is simply bad science, since it fails to address the likelihood of synergistic effects and even accumulating toxins in the food chain (14).

"Nonetheless, we applaud the fact that EFSA has asked Monsanto some hard questions in this case, having in the past demonstrated, over and again, that its GMO Panel is simply unfit for purpose (15). This represents progress.

"We are quite convinced that Monsanto has been fully aware, from the beginning, that line LY038 and line LY038 x MON810 are both dangerous; and yet they persisted with their applications until the extent of their scientific fraud was exposed to the public. We should not be surprised by this. The corporation pushes dangerous products onto the food market all the time, and does whatever is necessary to hoodwink the regulators into the belief

that all is well (16). We are convinced that Monsanto has other in-house studies which show that these varieties are unstable, unpredictable and harmful to health. Will we ever get to see these studies? No way!"

ENDS

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NOTES

(1) Based on information released under the Freedom of Information legislation. GM Free Cymru holds a folder containing all the key documents referred to in this Press Notice. GM crops have been "pulled" or withdrawn before -- for example the maize called Chardon LL -- but this is the first time this has happened specifically because of a request for new safety data from the regulators.

(2) <http://www.stuff.co.nz/national/3020246/Europe-balks-at-GE-corn-in-NZ>
This article highlights the key role played, over several years, by Prof Jack Heinemann and his team at Canterbury University's Centre for Integrated Research in Biosafety (INBI) in revealing the shortcomings of the Monsanto applications.

(3) <http://www.gmo-compass.org/eng/gmo/db/86.docu.html>
<http://www.gmo-compass.org/eng/gmo/db/85.docu.html>

"Second generation" GM crops, including those with supposedly enhanced nutritional value, are likely to be non-uniform and unstable because they have complex introduced traits. If two or more GM lines are hybridized to introduce "stacked" GM traits, the potential dangers become even greater because of synergistic effects. In spite of this, regulators simply assume them to be safe if the parental lines themselves have been approved for cultivation or food or feed use.

See: The Problem with Nutritionally Enhanced Plants, by David R. Schubert. Journal of Medicinal Food. December 2008, 11(4): 601-605.

<http://www.liebertonline.com/doi/abs/10.1089/jmf.2008.0094>

http://www.gmfreecymru.org/pivotal_papers/problem.htm

<http://www.bioscienceresource.org/docs/BSR-2-BGERvol23.pdf>

Transformation-induced Mutations in Transgenic Plants: Analysis and Biosafety Implications, by Allison K Wilson, Jonathan R Latham and Ricarda A Steinbrecher. Bioscience Resource Project.

The work of these independent scientists on so-called "genome scrambling" reveals how the genetic engineering of crops not only lacks precision but causes large scale genetic rearrangements of host DNA at transgene insertion sites, as well as large numbers of mutations scattered throughout the genome of each new transgenic plant. The significance of all this genetic damage is that the food safety of edible crops relies crucially on genetic stability.

<http://www.i-sis.org.uk/GE-maize.php>

(4) These letters are available as PDFs on request.

Brussels, 30 April 2009, from Renessen Europe SPRL

Re: Application for authorisation of genetically modified LY038 maize submitted IIIlder

Regulation (EC) No 1829/2003 - Withdrawal of Application EFSA-GMO-NL-2006-31

Brussels, 30 April 2009, from Renessen Europe SPRL

Re: Application for authorisation of genetically modified LY038 x MON810 maize submitted IIIlder

Regulation (EC) No 1829/2003 - Withdrawal of Application EFSA-GMO-NL-2006-32

(5) Submissions to FSANZ from INBI relating to the dossier for LY038:

Cretenet, M., Goven, J., Heinemann, J.A., Moore, B. and Rodriguez-Beltran, C.

2006. Submission on the DAR for Application A549 Food Derived from High-Lysine

Corn LY038: to permit the use in food of high-lysine corn.

www.inbi.canterbury.ac.nz

(6) Lucas, D. Petition for determination of nonregulated status for lysine

maize LY038 -- USDA/APHIS 2004 http://www.aphis.usda.gov/brs/aphisdocs/04_22901p.pdf

Agbios database for LY038 and LY038 + MON810. Site currently designated as high risk.

<http://www.biosafety-info.net/bioart.php?bid=358>

High lysine corn (LY038) deregulated in the US, but safety still in doubt

Why Not Transgenic High Lysine Maize by Professor Joe Cummins, ISIS Report 23/11/05

<http://www.i-sis.org.uk/highlysinemaize.php>

(7) <http://www.greens.org.nz/press-releases/nz-must-withdraw-approval-ge-food>

(8) <http://www.biotradestatus.com/default.cfm>

(9) Jeffrey Smith: "Genetic Roulette", pp 102-105 and Part 3, p 194
<http://www.seedsofdeception.com/utility/showArticle/?objectID=892>

Jack Heinemann: "Hope not Hype", see Chapter 4
<https://sites.google.com/site/therightbiotechnology/>

(10) Submission on APPLICATION A549 FOOD DERIVED FROM HIGH LYSINE CORN LY038: to permit the use in food of high lysine corn -----
Submitted to Food Standards Australia/New Zealand (FSANZ)
by New Zealand Institute of Gene Ecology
January 22, 2005

(11) Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission. Procedural Manual. 12th ed.
Rome: Food and Agriculture Organization of the United Nations : World Health Organization, 2001. Available
online <http://www.fao.org/DOCREP/005/Y2200E/y2200e00.htm>. Access date 31 May 2006.

(12) Letter from EFSA to Monsanto / Renessen -- Ref: Ref. PB/AC/ mt (2009) 3826240 and the Member States' comments submitted during the three-month consultation period on this application.

(13) <http://www.biosafety-info.net/bioart.php?bid=358>

(14) SMARTSTAX APPROVAL IGNORED RISKS
http://www.gmwatch.org/index.php?option=com_content&view=...artstax-approval-ignored-risks
http://www.organicconsumers.org/articles/article_18717.cfm
<http://www.foeeurope.org/GMOs/Seeds.htm>

Austrian Federal Department for Health: "A stacked organism has to be regarded as a new event, even if no new modifications have been introduced. The gene-cassette combination is new and only minor conclusions could be drawn from the assessment of the parental lines, since unexpected effects (e.g. synergistic effects of the newly introduced proteins) cannot automatically be excluded. Furthermore, it should not be neglected that two of the parental

lines, GM maize MON89034 and GM maize MON88017, have not yet gained authorisation within the European Union."

<http://www.gmwatch.org/latest-listing/1-news-items/11359-smartstax-in-europe>

(15) http://www.gmfreecymru.org/open_letters/Open_letter10Dec2007.htm

OPEN LETTER, "EFSA is not fit for purpose "

From GM-Free Cymru to Catherine Geslain-Laneelle Executive Director, EFSA Parma Italy, 10th December 2007

(16) http://www.gmfreecymru.org/pivotal_papers/quotes.html

More evidence of Scientific Malpractice in GM assessment process

Under wraps

NATURE BIOTECHNOLOGY, VOLUME 27, NUMBER 10, October 2009

http://www.emilywaltz.com/Biotech_crop_research_restrictions_Oct_2009.pdf

The Genetic Engineering of Food and the Failure of Science – Part 2:

Academic Capitalism and the Loss of Scientific Integrity

by Don Lotter Int. Jnl. of Soc. of Agr. & Food, Vol. 16, No. 1, pp. 50–68

http://www.gmfreecymru.org/pivotal_papers/academic_capitalism.html

Exposed: Monsanto's fraudulent safety tests for GM Soy

http://www.gmfreecymru.org/pivotal_papers/exposed.htm

Abuse of the Scientific Method Seen in Monsanto Aspartame Research

<http://www.holisticmed.com/aspartame/abuse/>

Criminal Investigation of Monsanto Corporation - Cover-up of Dioxin

Contamination in Products - Falsification of Dioxin Health Studies.

<http://www.purefood.org/dioxcov.html>