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ISIS Press Release 26/07/07

Transgenic Plum Gets USDA Non-regulated Status Based on False Claims of Safety

[Prof. Joe Cummins](#) and [Dr. Mae-Wan Ho](#) rebut USDA conclusion that transgenic DNA and RNA are non-toxic

USDA deregulates its own transgenic plum despite overwhelming public objection

The United States Department of Agriculture Animal and Plant Health Inspection Service (USDA/APHIS) has recently granted non-regulatory status to a transgenic plum resistant to plum poxvirus [1] after receiving 1 725 comments from state farm bureaus, organic growers, growers associations, consumer groups, agriculture support industries, academic professionals and individuals, with respondents against the petition (1 708) outnumbering those in favour (17) by a factor of 100 to 1.

APHIS was clearly biased in favour of the petition in their Environmental Assessment, and attempted to justify its decision by stating: "The majority of academic researchers, as well as the state farm bureaus that submitted comments, support granting non-regulated status to the C5 plum. The majority of those who submitted comments opposing granting non-regulated status were submitted by organic grower or consumer groups, organic growers, those who favour organic agriculture or those who are opposed to genetic engineering technology in general."

Deregulation based on obsolete and irrelevant FDA notice



APHIS maintains that, in general RNA and DNA have no toxic properties [1] based primarily on a Food and Drug Administration (FDA) 1992 GRAS notice on transgenic microbes used to produce animal proteins under contained conditions, which is irrelevant and highly misleading when applied to environmental release in the case of the C5 transgenic plum. More importantly, the FDA notice is obsolete in view of numerous scientific findings made since, and its recommendations should be rejected forthwith. For example, the extensive regulatory role of small RNA molecules, similar to those in the virus resistance of C5 plums, was not mentioned in the FDA notice, as it had not yet been discovered; nor indeed, the potentially fatal effects of such RNA molecules in mammals highlighted in our detailed comment to the USDA [2] ([USDA Proposes to Deregulate Its Own Transgenic Plum](#), *SiS* 31).

Despite the fact that a small RNA molecule was present in high concentrations in the transgenic plum, APHIS maintains that: "Nucleic acids (i.e., RNA and DNA) are present in all living organisms and are not known to have any toxic properties. Nucleic acids are considered to be "generally recognized as safe" (GRAS) by the U.S. Food and Drug Administration (FDA) (FDA 1992) and exempt from the requirement of a tolerance under the Federal Food Drug and Cosmetic Act by the U.S. Environmental."

APHIS dismissed comments questioning the safety of the small RNAs responsible for providing resistance in C5 plum, including one comment from us

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[2] pointing to the use of small RNAs in RNA interference (RNAi) gene therapy and its potential adverse health effects. APHIS insists that, "the safety of nucleic acids is widely accepted", as both RNA and DNA are part of all food products that we consume; further, "given that plant viruses infect a tremendous amount of the fruits and vegetables that we consume, it is highly likely that humans have been exposed to the same or similar viral RNA that may be expressed in a coat-protein expressing plant." As to the concern about safety arising from findings in RNAi gene therapy, APHIS states that such RNAs "would be specifically designed and intended for targeted use in humans, and they would be significantly different than those found in the C5 plum."

All of the APHIS statements cited are false and or misleading, and are contradicted by extensive scientific literature.

Small RNAs *are* potentially lethal to mammals

It is questionable whether people tend to eat virus-infected fruits and vegetables; also, potentially toxic small RNA molecules are produced, *not* by the virus but by the transgenic plum as the result of the insertion of viral DNA into the plum genome. Virus infected non-transgenic plums would not make large quantities of the small RNA that prevents virus replication.

There is substantial evidence that the small RNA molecules may be toxic to animal cells (see below), and produce off target effects in plants. Contrary to the statement made by APHIS (above) suggesting that specific sequences were designed for gene therapy, the researchers tested *many* different RNA sequences for toxicity to mice. Out of 49 sequences tested, the majority (36) were severely toxic, 23 were lethal in every case, killing the animals within two months [3] ([Gene Therapy Nightmare for Mice](#), *SiS* 31). The fact is, the small RNA molecules produced in the transgenic plum have never been tested for their toxicity in animals and they have not previously been produced in quantities in non-transgenic plums or any other crop plants. The potential toxicity of small RNAs is featured in a number of publications between 2004 and 2006 [4-9], which show that APHIS' conclusion that RNA molecules are safe for humans is false and invalid.

Toxic DNA a fact of life

APHIS further maintains that DNA molecules are intrinsically non-toxic based on the 1992 FDA GRAS notice [1]. Even though toxic DNA is not a major issue in the transgenic plum, it is worth pointing out that the toxicity of certain DNA molecules is well established [10-12]. DNA molecules are recognized by the immune system as a means of activating defence against pathogenic bacteria and viruses. A strong immune reaction is triggered; even one leading to death in mammals, as stated in a report published in 2004 [13]:

"The mammalian innate immune system has the ability to recognise and direct a response against incoming foreign DNA. The primary signal that triggers this response is unmethylated CpG motifs present in the DNA sequence of various disease-causing pathogens. These motifs are rare in vertebrate DNA, but abundant in bacterial and some viral DNAs. Because gene therapy generally involves the delivery of DNA from either plasmids of bacterial origin or recombinant viruses, an acute inflammatory response of variable severity inevitably results. The response is most serious for non-viral gene delivery vectors composed of cationic lipid-DNA complexes, producing adverse effects at lower doses and lethality at higher doses of complex."

APHIS' conclusion on the lack of toxicity of DNA is evidently also false and misleading.

We have stated on many occasions (most recently in [GM Food Nightmare Unfolding in the Regulatory Sham](#) [14], ISIS scientific publication) that transgenic DNAs, as opposed to non-transgenic DNA, share certain features that make them potentially unsafe.

- Sequence homologies to many species including pathogenic bacteria and viruses, which enhances horizontal gene transfer and recombination to create new pathogens
- Antibiotic resistance marker genes that could transfer horizontally to pathogenic bacteria and render infections untreatable

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- Recombination/fragmentation hotspots such as the CaMV 35S promoter that further enhance horizontal gene transfer and recombination
- Insertion sequences that enable transgenic DNAs to invade genomes and transfer horizontally
- Strong viral promoters that could activate oncogenes and trigger cancer.

A string of false and invalid claims on safety

In conclusion, APHIS has falsely claimed that RNA and DNA molecules are intrinsically safe for humans, based solely on an obsolete FDA notice now refuted by numerous observations.

This is the latest in a long string of false and invalid claims on safety from the USDA. ISIS has submitted at least 34 detailed objections containing safety warnings against deregulation or field releases of genetically modified organisms (GMOs) to the USDA and other US regulatory agencies since 2001 [15], all to no avail. The same goes for ISIS' submissions to the European Food Safety Authority and the UK Food Safety Authority [14].

However, the US judiciary system appears to be catching up with USDA's cavalier attitude towards environmental safety assessment [16] ([Approval of GM Crops Illegal, US Federal Courts Rule](#), *SiS* 34), and has imposed the first ban on a GM crop (alfalfa) in the country. The US has joined the avalanche of bans and moratoriums hitting GM crops around the world over the past year as policy makers are waking up to the irrefutable mass of evidence piling up on the hazards inherent to GMOs [14, 17, 18] ([No to GMOs, No to GM Science](#), *SiS* 35; [GM Science Exposed: Hazards Ignored, Fraud, Regulatory Sham, and Violation of Farmers' Rights](#). ISIS CD book).

References

1. Approval of USDA-ARS Request (04-264-01P) Seeking a Determination of Non-regulated Status for C5 Plum Resistant to Plum Pox Virus, Finding of No Significant Impact and Decision Notice. *Federal Register* 72, No. 134 / Friday, July 13, 2007 / Notices.
2. Cummins J. and Ho MW. USDA proposes to deregulate its own transgenic plum. [Science in Society](#) 31, 5-7, 2006.
3. Ho MW. Gene therapy nightmare for mice could human be next? [Science in Society](#) 31, 25, 2006.
4. Grimm D, Streetz KL, Jopling CL, Storm TA, Pandey K, Davis CR, Marion P, Salazar F, Kay MA. Fatality in mice due to oversaturation of cellular microRNA/short hairpin RNA pathways. *Nature* 2006, 441(7092), 537-41.
5. Marsden, P. RNA interference as potential therapy — not so fast. *N Engl J Med* 2006, 355, 953-4.
6. Barik S. RNAi in moderation. *Nat Biotechnol.* 2006, 24(7), 796-7.
7. Sнове O Jr, Rossi JJ. Toxicity in mice expressing short hairpin RNAs gives new insight into RNAi. *Genome Biol.* 2006, 7(8), 231.
8. Fish RJ, Kruithof EK. Short-term cytotoxic effects and long-term instability of RNAi delivered using lentiviral vectors. *BMC Mol Biol.* 2004, 5(9), 1-15
9. Jackson AL, Burchard J, Schelter J, Chau BN, Cleary M, Lim L, Linsley PS. Widespread siRNA "off-target" transcript silencing mediated by seed region sequence complementarity. *RNA* 2006, 12(7), 1179-87.
10. Luyer MD, Buurman WA, Hadfoune M, Wolfs T, van't Veer C, Jacobs JA, Dejong CH, Greve JW. Exposure to bacterial DNA before hemorrhagic shock strongly aggravates systemic inflammation and gut barrier loss via an IFN-gamma-dependent route. *Ann Surg.* 2007, 245(5), 795-802.
11. Obermeier F, Dunger N, Deml L, Herfarth H, Schölmerich J, Falk W. CpG motifs of bacterial DNA exacerbate colitis of dextran sulfate sodium-treated mice. *Eur J Immunol.* 2002, 32(7), 2084-92
12. Khazanov E, Simberg D, Barenholz Y. Lipoplexes prepared from cationic liposomes and mammalian DNA induce CpG-independent, direct cytotoxic effects in cell cultures and in mice. *J Gene Med.* 2006, 8(8), 998-1007.
13. Yew NS and Cheng SH. Reducing the immune stimulatory activity of CpG-containing plasmid DNA vectors for non-viral gene therapy. *Expert Opin Drug Deliv.* 2004, 1(1), 115-25.
14. Ho MW, Cummins J and Saunders PT. GM food nightmare unfolding in the regulatory sham. *Microbial Ecology in Health and Disease* 2007, 19(2), 66 – 77.
15. List of ISIS submissions to USDA and other US regulatory agencies.

1. [USDA Poised to Deregulate Illegal GM Rice](#), *SiS* 32, 2006.
2. [USDA Proposes to Deregulate Its Own Transgenic Plum](#), *SiS* 31, 2006.
3. [GM Sugar Beet Gone Sour](#), *SiS* 25, 2005.
4. [GM Eucalyptus Environmental Assessment Irregular](#), *SiS* 35, 2007
5. [Dangerous Field Test of Non-pathogenic GM Bacteria](#), *SiS* 35, 2007.
6. [Deregulation of Glyphosate Tolerant Creeping Bentgrass Out of Question](#)
7. [Death Domains in New Bio-pesticides](#), *SiS* 26, 2005.
8. [Best Practice in the Design of GM Crops](#), ISIS Report, 2000, <http://www.i-sis.org.uk/gmdesign.php>
9. [GM Maize 59122 Not Safe](#), *SiS* 34, 2007.
10. [GM Safflower with Human Pro-Insulin](#), *SiS* 35, 2007.
11. [MON88017 Another MON863?](#), ISIS Report, 2005, <http://www.i-sis.org.uk/mon.php>
12. [Antibodies from Hybrid GM Tobacco Plants](#), *SiS* 35, 2007.
13. [Field-testing Bacterial Pathogens and Fungus](#), ISIS Report, 2005, <http://www.i-sis.org.uk/fieldTest.php>
14. [Comment on Assessment ReportC/GB/02/M3/03](#), ISIS Report, 2004, <http://www.i-sis.org.uk/CaliforniaLetter.php>
15. [Transgenic Pink Bollworms FONSI?](#), ISIS Report, 2001, <http://www.i-sis.org.uk/pinkbollworms.php>
16. [Comments on: Environment Assessment: Confined field study of a ...](#), ISIS Report 2001, <http://www.i-sis.org.uk/bollworm.php>
17. [ISIS News no.9/10 - Stop Release of GM Insects](#). ISIS Report, 2001 <http://www.i-sis.org.uk/isisnews/i-sisnews9-2.php>
18. [piggyBac a name to remember](#), ISIS Report, 2001, <http://www.i-sis.org.uk/piggybac-pr.php>
19. [No Bt Resistance?](#) *SiS* 20, 2003.
20. [Pharm Crop Products In US Market](#), *SiS* 23, 2004.
21. [More on Bt Resistance](#), ISIS Report, 2003, <http://www.i-sis.org.uk/MoreBtresistance.php>
22. [The full significance of theA normally harmless bean protein, a ...](#), ISIS Submission to many regulatory bodies, 2005, <http://www.i-sis.org.uk/TPTMMI.php>, also [Transgenic Pea that Made Mice Ill](#), *SiS* 29, 2006
23. [Why Not Transgenic High Lysine Maize](#), *SiS* 29, 2006.
24. [No to GM Oilseed Rape GT73](#), *SiS* 24, 2004.
25. [Chronicle of An Ecological Disaster Foretold](#), *SiS* 18, 2003.
26. [ISP Bid to Stop US "Rubber-Stamping" Transgene Contamination](#), *SiS* 25, 2005.
27. [GM Pharmaceuticals from Common Green Alga](#), *SiS* 28, 2005.
28. [Terminator insects unleash genome invaders with wings](#), ISIS Report, 2001, <http://www.i-sis.org.uk/terminsects-pr.php>
29. [Terminator Insects – The Killing of Females](#), ISIS Report, 2001, <http://www.i-sis.org.uk/sterileinsect.php>
30. [Is FDA Promoting or Regulating Cloned Meat and Milk?](#) *SiS* 33, 2007.
31. [Bt Toxins in Genetically Modified Crops: Regulation by Deceit](#), *SiS* 22, 2004.
32. [GM Crops and Microbes for Health or Public Health Hazards?](#), *SiS* 33, 2007.
33. [GM Crops for Health?](#) ISIS Report, 2006, http://www.i-sis.org.uk/GM_Crops_for_Health.php
34. [Moratorium on all GM Trees and Ban on GM Forest Trees](#), ISIS Report, 2007, http://www.i-sis.org.uk/Moratorium_on_all_GM_Trees.php
16. Cummins J and Ho MW. Approval of GM crops illegal, US federal courts rule. [Science in Society](#) 34, 24, 2007.
17. Ho MW. No to GMOs, no to GM science. [Science in Society](#) 35 (to appear).
18. Ho MW, Cummins J, Burcher S, Gala R, Lim LC, et al. *GM Science Exposed: Hazards Ignored, Fraud, Regulatory Sham, Violation of Farmers' Rights*, Compilation from Science in Society archives, 2003-2007, ISIS CD Book, <http://www.i-sis.org.uk/includes/frontpage11.htm>



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