

MON863 Corn: A case study in incompetence

Food Standards Australia New Zealand (FSANZ) approved this GE corn variety in 2003. Since then, a Monsanto study emerged which found that rats fed with MON863 suffered a number of abnormal effects, including smaller kidneys and variations in blood composition.ⁱ Today a new peer reviewed study of Monsanto's original data, by a team of experts headed by Professor Seralini, will be published in the *journal Archives of Environmental Contamination and Toxicology*. The study confirms that rats fed the GE corn variety MON863 showed signs of kidney and liver toxicity. FSANZ had access to this data in 2004 but failed to evaluate it and instead relied on Monsanto's analyses which, according to Professor Seralini, "do not stand up to rigorous scrutiny."

FSANZ's safety assessment

According to FSANZ, it did not receive the rat study when they were assessing MON863, even though the study was complete at the time of Monsanto's application.ⁱⁱ It therefore based its safety assessment on an acute oral toxicity study using mice and a feeding study using chickens. The mouse study used *Cry3Bb1* produced in an *E.coli* fermentation system rather than that isolated from MON863 corn. The protein produced was also biochemically different to that expressed in MON863 corn, but the scientists predicted that this would not affect the outcome of the toxicity study. No evidence was provided to back up this assumption.ⁱⁱⁱ The basis for this study is the assumption that the only difference between MON863 and its parental line is the expression of *Cry3Bb1* protein. This assumption remains untested. There are numerous examples of where genetic engineering has produced unexpected effects in plants.^{iv}

Despite the obvious flaws in its safety assessment, FSANZ stated that "no further data was deemed necessary or requested"^v. It went on to add that "FSANZ does not require feeding studies in animals, such as this 90-day feeding study in rats, to be submitted as part of an application to FSANZ for a GM food. Where GM varieties have been shown to be compositionally equivalent to conventional varieties, feeding studies using target livestock species will add little to a safety assessment and are generally not warranted." Nevertheless, as a result of public pressure FSANZ asked Monsanto to provide the summary, supplemental analyses and raw data from the feeding study. It stated that "this combined material will be fully evaluated by FSANZ once all studies are received."^{vi} Despite the serious nature of the concerns, FSANZ failed to reassess its approval of the corn.^{vii}

FSANZ received the raw data from Monsanto on 22nd September 2004 and sent it back nine days later.^{viii} According to FSANZ, it “obtained all of the data on the corn feeding study in rats from Monsanto...however, it was requested that this data be kept confidential. FSANZ decided that the confidentiality claim by Monsanto was not justified under the FSANZ Act and the raw data was returned to Monsanto.”^{ix} When FSANZ sent the feeding study back it was not only abrogating its own responsibility, it was protecting Monsanto as well, by trying to ensure that critical public information remained buried.

FSANZ claimed that, in the 7 working days before the document was returned, it was able to compare the information contained in the 1,139 page study with that in the summary. FSANZ claims that “the full data adds little in terms of any further information to that already provided in the summary of the data”.^x

According to FSANZ, it has “assessed all the available information on MON863 corn and determined that there are no human health and safety concerns with the consumption of this corn”^{xi} an opinion that contrasts starkly with that held by many European countries.^{xii}

ⁱ Lean, G. (2005) Revealed: Health Fears Over Secret Study Into GM Food, *The Independent*, 22/5/05, available at: www.gmwatch.org/archive2.asp?arcid=5302, viewed 10/6/05.

ⁱⁱ FSANZ (2004) Monsanto MON863 corn safety assessment, 17/9/04,

www.foodstandards.gov.au/mediareleasespublications/factsheets/factsheets2004/monsantomon863cornsa2571.cfm, viewed 10/6/05.

ⁱⁱⁱ FSANZ (2003) Final Assessment Report: Application A484: Food from insect protected MON863 corn, p. 39, www.foodstandards.gov.au/srcfiles/A484_Final_Assessment_Report.pdf, viewed 10/6/05.

^{iv} See Greenpeace (2002) GE Food: Safe to Eat?, www.greenpeace.org.au/truefood/downloads/ge_food_safetoeat.pdf

^v FSANZ (2004)

^{vi} *Ibid.*

^{vii} Dr Paul Brent, Manager, Product Safety Standards Section, Food Standards Australia New Zealand pers. comm.

^{viii} *Ibid.*

^{ix} Peter Abbott, Scientific Risk and Evaluation Branch, FSANZ, pers. comm.

^x Dr Paul Brent, Manager, Product Safety Standards Section, Food Standards Australia New Zealand pers. comm.

^{xi} *Ibid.*

^{xii} EU (2005)