

Madeleine Love
Researcher, MADGE Australia Inc
www.madge.org.au
info@madge.org.au

23 December 2009
Updated for Web Posting 17 January 2010

[]
GM Advisor
The Office of the Hon Tony Burke
Minister for Agriculture, Forestry and Fisheries
Australian Parliament House
Canberra ACT 2600

Dear [GM Advisor],

This letter and collection of studies is long-promised from our meeting in Parliament House Canberra on October 26 this year. I'd offered the information that animals raised on feed provided by Monsanto had adverse outcomes with higher death rates, and you had expressed an interest in seeing them.

It's taken a while to work out how best to write up this material. We wanted it to be friendly and readable by people who were newer to the GM issue. I've tried to point to a few key things about the studies to bring home the message. All the detailed material is being provided, so anyone wanting to read right into it can do so (and we recommend this if impartial resources are available).

At our meeting I said that MADGE had written a summary of these studies in easy-read style. There have been additional comments made within this summary, to add more information for your use (see attached). I've used the Verdana font on a 10% grey background to highlight the comments.

A red arch file will arrive in the post containing hard copies of the studies and Monsanto data. Anyone with interest could read it all, but I'm only going to refer to a few lines and sections to provide evidence for the important points.

In short, there have been reports on four animal production studies using GM RR canola. Two were done by Monsanto (trout & chickens), one by collaborating bodies in Canada on lambs using GM and non-GM feed prepared and provided by Monsanto, and there is an abstract report of a similar study done in Canada on pigs.

Where the Monsanto data was explicitly available we can read that the feeds were contaminated and differentially prepared at Monsanto's will. Monsanto failed to provide full information on deaths and removals from the studies. There is no information that can be learnt from the studies, except that farmers should not feed their animals on feed prepared by Monsanto!

However, the material provides clear information on the lengths to which Monsanto has gone to prevent information about the feed value of their GM RR canola crop emerging, and their preparedness to use corrupt feed and practices, and to report on it.

I wrote this email to WA and SA politicians recently which will paint a picture for you...

Dear Members of WA Parliament

Re: GM RR canola

The Office of the Gene Technology Regulator sent me the Monsanto data for the GM RR canola chicken production study [1]. I've been reading through it.

Monsanto self-reported that their commercial comparison feed was GM contaminated [p19], and wrote that the mortality rates in the trial were slightly higher than expected [p6]. They also failed to provide full information on all of the removals from the study.

It worries me that the OGTR didn't report what Monsanto self-reported.

If in future, poultry and livestock producers (and perhaps humans) are looking for someone to sue for adverse outcomes from GM canola feed, it might be difficult to sue Monsanto, given Monsanto provided full information about their inappropriate study conduct. We could only sue our own government bodies.

It doesn't appear that FSANZ received this material, but they received equally compromised material which was self-reported by Monsanto - I just have to write it all up.

There's no clear work on which to base decisions, and it would be better to err on the side of precaution, trusting the broadly held rejection by the WA people.

Best wishes,

Madeleine Love

MADGE Australia Inc Researcher
www.madge.org.au
info@madge.org.au

[1] MSL No.:17538; Stanisiewski et al 2001; Monsanto Company, Product Safety Centre, Biotechnology Regulatory Sciences.

Best wishes,

Madeleine Love
Researcher, MADGE Australia Inc; www.madge.org.au, info@madge.org.au

Attachments:

"GM RR Canola Animal Studies.doc"

The studies and Monsanto data will be posted to Australian Parliament House this morning in hardcopy (red arch file).

Summary and Guide to animal feeding studies reporting to use products of Monsanto's GM RR canola (line GT73) ...Revised 17/1/10

This has been prepared by Madeleine Love of MADGE Australia Inc for [], GM Advisor to the Hon Tony Burke, Federal Minister for Agriculture, Forestry and Fisheries: 22 December 2009

Preliminary note: The commercial GM canola presently grown in Australia is called "Roundup Ready", and when not being technical, the terminology I often use is GM RR canola, where RR = Roundup Ready. More formally, in FSANZ and OGTR material, the line is known as "GT73" where GT = Glyphosate Tolerant (glyphosate is the active component of the herbicide Roundup that can be sprayed on the crop). Sometimes the crop is denoted as RT73 where RT = Roundup Tolerant.

Animal Studies Conducted on Monsanto's GM Roundup Ready (RR) Canola

Firstly, here is a summary on the type of animal studies one is likely to see conducted on GM crops:

Animal Feeding Trials

In an animal GM feeding trial, typically, feed derived from a GM crop and its non-GM counterpart is fed to animals. Various aspects of the animals may be measured to see if the GM variety has affected the animal differently.

Human Health Variables

Some animal studies look at human health variables, such as identifying the concentration of immune cells in digestive tract tissues, or assessing alterations in liver tissue profiles. They are quite detailed examinations of the health response in the animal to GM feed, and the findings may have some relevance to human health.

Production Variables

Animal feeding production trials typically proceed for a number of weeks or a few months. They are examining whether the animal will survive to slaughter, and the quality of the animal products. The outcomes of these studies may be helpful for animal producers.

The four published animal feeding trials conducted with Monsanto's GM RR canola all looked at 'production' variables. That is, the trials examined size of chicken breasts or tenderness of lamb chops or feed efficiency - how much feed per kg of carcass?

These four animal production studies have looked at trout, chickens, pigs and lambs/sheep, and they will be discussed below

I began to look for studies about two years ago, and a year ago believed I had them all (4 of them). After meeting [GM Advisor] in October I began another search to be sure. I contacted DAFF and asked if they knew of any formal or informal studies

conducted on GM RR canola – apart from the initial correspondence I didn't hear anything more from them – I wasn't expecting anything. I also went carefully through the OGTR GM RR canola RARMP document. The document referred to the Monsanto data for the chicken study which I hadn't received from FSANZ. The OGTR provided this material on request and it has been very revealing¹.

In recent weeks there has been a furor in the WA political world and media over the progress of an independent GM RR canola study on rats looking at human health endpoints, partly funded by the WA government. The study is being conducted by the Institute of Health and Environmental Research, principal researcher, Dr Judy Carman. The main pro-GM protagonist has been Dr Ian Edwards of Edstar Genetics (we understand it is a private GM firm). He has made statements saying there have been hundreds of studies showing it is safe. After reading Dr Edwards comments in the media² I rang him to ask what studies he was referring to. We have previously been through lists of studies referred to by the WA Government and found nothing on GM RR canola within them³. [NB: Every GM crop is a random event, and that is why the crop lines are often called 'Events' – they can't be repeated. As a result every individual GM Event is required to be separately tested.]

He referred me to two papers, published a day or two later in Farm Weekly⁴. I already had one of these compilations and it contained no studies on GM RR canola⁵. I purchased the other compilation (by the European Food Safety Authority), and it contained references to these same four studies (trout, chickens, lambs and pig-abstract)⁶. It also contained a reference to a 1996 rabbit digestibility paper, conducted on a GM oilseed rape. I don't know if this was GM RR canola, and wasn't able to find the paper (from the Sixth World Congress on Rabbits held in Toulouse) – I don't think it will provide any further information, and have decided not to pursue it at this time. The rabbits are doing quite well in Australia.

Other Variables

Five other studies on GM RR Canola have been conducted by four collaborating Canadian Agricultural research institutions, looking at the more scientific aspects of the digestion of DNA in sheep and pigs. The culminating study found fragments of GM canola DNA in the digestive tissues of sheep and pigs and in the liver and kidney of pigs.

The line of inquiry follows an interesting course and is discussed briefly below.

¹ MSL No.:17538; Stanisiewski et al 2001; Monsanto Company, Product Safety Centre, Biotechnology Regulatory Sciences.

² Farm Weekly 26/11/09

³ WA Agriculture Minister using phantom studies and Monsanto data to reassure public over GM canola <http://www.madge.org.au/Docs/MR-phantom-studies-280109.pdf>

⁴ Farm Weekly 3/12/09

⁵ Studies on feeds from genetically modified plants (GMP) – Contributions to nutritional and safety assessment; G. Flachowsky, K. Aulrich, H. Böhme and I. Hall Animal Feed Science and Technology Volume 133, Issues 1-2, 1 February 2007, Pages 2-30; http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T42-4KWTFD8-3&_user=10&_rdoc=1&_fmt=&_orig=search&_sort=d&_docanchor=&view=c&_searchStrId=1123678781&_rerunOrigin=google&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=1a623777203119fd4d5c20bd57ace8e2

⁶ Safety and nutritional assessment of GM plants and derived food and feed: the role of animal feeding trials.; EFSA GMO Panel Working Group on Animal Feeding Trials. Food Chem Toxicol. 2008 Mar;46 Suppl 1:S2-70. Epub 2008 Feb 13. <http://www.ncbi.nlm.nih.gov/pubmed/18328408>

Four Animal Production Trials with GM RR Canola

A critical factor in these four studies is that Monsanto supplied the GM feed, and feed from the non-GM counterpart for comparison. Each of these studies depended on the integrity of this feed.

The importance of this in the whole testing process can't be over-stated. Monsanto has control of this material under patent. I only have detailed information of the way feed was produced in respect of the first study on trout. It was raised from scratch in the 1992 Canadian trials, and is detailed below.

There is a great amount of detail in each study, and we are selectively reporting some of the details that concern us from a procedural or human health perspective. There is a lot of other detail that may be useful for people who are reading from other angles of interest.

If you want to investigate this further we encourage you to read deeply into the full text of the studies - only selected results are published in the free abstracts provided on the web.

The full texts of the chicken and lamb studies are available free on the web, but the trout study was bought at a price. Copyright conditions prevent us from publishing the studies on the web. You may be able to read the full text for free at a University with journal access - contact us if you'd like advice on how to do this. The full text of the pig study does not seem to be available, but we can deduce a few things about the study.

The Trout Study

Brown PB, Wilson KA, Jonker Y, Nickson TE. (2003) Glyphosate tolerant canola meal is equivalent to the parental line in diets fed to rainbow trout. *J Agric Food Chem*. 51:4268-72
<http://pubs.acs.org/doi/abs/10.1021/jf034018f>

This study reported on two trout feeding studies. The first took place in 1993, using seed raised in the 1992 Canadian Field Trials. It had been conducted by Monsanto⁷ with the support of Purdue University (Indiana) as a regulatory requirement imposed by Canada⁸. This study was described in detail in material provided by Monsanto to Food Standards Australia New Zealand (then ANZFA).

Information on the growing of the seed, and on the processing of the seed into meal for the feeding study is in a 440 page pdf document supplied by FSANZ. The manner in which the canola meal was produced for this trial was outrageous.

It is not the place to detail this astonishing record here. In short, the different GM and non-GM varieties were grown side by side in plots at a number of sites in Canada. The feed

⁷ MSL-13063; Evaluation of Glyphosate Tolerant Canola as a Feed for Rainbow Trout; Brown PB, Wilson KA, Nickson TE

⁸ Evaluation of Glyphosate-tolerant Canola Lines from the 1992 Canadian Field Trials; Nickson TE et al, Monsanto; Attachment #3: Protocol #92-02-30-01 for Experiment #92-447-702 "Processing Roundup-Tolerant Canola (RTC) and Control Westar Seed from the 1992 Canadian Field Tests."

used in the trials was grossly contaminated, so much so that the trials had to be repeated. The seed was reported to have been 'mixed'.⁹ Recently revised protocols allowed for the toasting of the canola meal "at the option of the Sponsor" (Monsanto). Monsanto self reported differential processing of meal.

I'll detail some of the record here – this *is* the place for it. After reading this, it will be impossible to think of Monsanto as a body capable of conducting its own rigorous independent study on the product by which it hopes to profit.

It always screamed corrupt to me that information provided by a GM crop developer would be treated as though it was credible, with no alternative information sought. There have been studies clearly demonstrating bias in the medical field when researchers or funding has come from the company with the commercial interest. This is one frequently quoted¹⁰.

Nonetheless, FSANZ relied 100% on this material for human health and safety assessment. There was no independent alternative – we don't understand why a body charged with food safety didn't immediately reject the material. The OGTR relied on the material for safety for agricultural workers and for approval for use as an animal feed, despite the clear and documented lack of integrity of the company involved. Both FSANZ and the OGTR referred to this study as evidence. We haven't seen any evidence to say they read into the material any further than the abstract. Each body had the right to commission its own research, but chose not to^{11 12}.

Given that I have read, and soon you will read, the sort of practices employed by Monsanto to raise this feed, knowing that both FSANZ and the OGTR have failed to comment on the practices presented here, I have to ask the question 'who owns these bodies?' But that's for another place and time.

The other question that should be settled here is why there is no alternative independent information. It has been long understood that independent research has been restricted by the GM crop developers, and that independent researchers are liable to be harassed by the GM developers, but detailed referenced information about these practices has only emerged in the last few months in the trade journal "Nature Biotechnology"¹³. The article described the many practices adopted by the GM developers to discourage independent research on their products and prevent publication of unfavourable results. We're not sure why the information has come out at this time, but there is a huge battle between the GM crop developers in the US at the moment over patents, property and monopoly, and we think they were spilling each other's beans. A week later more information emerged in the journal "New Scientist"¹⁴.

⁹ This end of this paragraph formerly read "Protocols had been specially changed for the processing of the seed into meal, leading to the toasting of meal at greater levels of heat "at the option of the Sponsor" (Monsanto)." It has been altered in response to receipt of more complete data.

¹⁰ Association of funding and conclusions in randomized drug trials: a reflection of treatment effect or adverse events?; Als-Nielsen B et al; JAMA, 2003 Aug 30;290(7):921-8

¹¹ FSANZ: Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants CAC/GL 45-2003 <http://bit.ly/4xyTqC>; Principles for the risk analysis of foods derived from modern biotechnology CAC/GL 44-2003 <http://bit.ly/3Q1x3J>

¹² OGTR : Senate Estimates <http://www.aph.gov.au/hansard/senate/commtee/S7055.pdf> CA144-CA162

¹³ Under wraps; Emily Waltz; *nature biotechnology* volume 27 number 10 october 2009; Article can be read in full here: http://www.emilywaltz.com/Biotech_crop_research_restrictions_Oct_2009.pdf

¹⁴ Stop selling out science to commerce; Parkinson S & Langley C; *New Scientist*; 9/11/09; Issue 2733

Onto the material:

Background: Homozygous/Heterozygous

When the GM RR canola GT73 cropline was first developed only one of a pair of chromosomes contained the GM 'cassette'. The plant was isolated and self-pollinated, producing the expected variety in the seed. Some seed would contain the GM cassette on 2 paired chromosomes (homozygous GM), some one copy (heterozygous GM); there would also be seed which did not contain the cassette.¹⁵

I understand that GM RR canola seed provided to farmers is from a homozygous source (GM cassette on paired chromosomes), otherwise a good proportion of their planted seed would die off when sprayed with roundup. Animals eating this processed seed would be subject to the full-strength quantities of GM proteins and DNA. Heterozygous seed is reported to contain a bit more than half the quantities of GM proteins (and one would suppose, half the GM DNA).

Background on cross-pollination

Canola pollen has been described by the OGTR as being 'half-way' between heavy, sticky insect pollen, and light blowable wind pollen¹⁶. This document cited sources saying that successful pollination from other canola plants may run at 12-47%.

Studies in the OGTR RARMP document¹⁷ unflinchingly reported that although cross-pollination declined quite rapidly over 10's of metres, it continued for kilometres.¹⁸ Studies looking at long distance transfer of canola pollen found contamination at the furthest distances examined (4km, 26km), and canola pollen in the air 4km from the nearest source¹⁹.

So GM and non-GM canola planted within 10m will experience cross-pollination – planted within 1.5m there may be substantial contamination.

What would we expect of the feed in an animal feeding trial?

There are a lot of conditions for these sorts of animal feeding trials, but as the minimum... We'd expect animals to be trialed on uncontaminated GM RR canola feed of the type under consideration. We'd expect a matched group of animals to be trialed on uncontaminated non-GM canola feed from the parent plant (that from which the

¹⁵ Evaluation of Glyphosate-tolerant Canola Lines from the 1992 Canadian Field Trials; Nickson TE et al, Monsanto; Attachment #7: Canola Definition Pedigree

¹⁶ The biology and ecology of canola (*Brassica napus*) July 2002; Office of the Gene Technology Regulator [http://www.health.gov.au/internet/oqtr/publishing.nsf/Content/canola-3/\\$FILE/brassica.pdf](http://www.health.gov.au/internet/oqtr/publishing.nsf/Content/canola-3/$FILE/brassica.pdf)

¹⁷ General Release of Roundup Ready canola (*Brassica napus*) in Australia; Dir 020/2002; [http://www.health.gov.au/internet/oqtr/publishing.nsf/Content/dir020-3/\\$FILE/dir020finalrarm.pdf](http://www.health.gov.au/internet/oqtr/publishing.nsf/Content/dir020-3/$FILE/dir020finalrarm.pdf)

¹⁸ Ramsay, G., Thompson, C., and Squire, G. (2003). Quantifying landscape-scale gene flow in oilseed rape. Report No. Final Report of DEFRA Project RG0216: An experimental and mathematical study of the local and regional scale movement of an oilseed rape transgene., Department for Environment, Food & Rural Affairs, UK, <http://www.defra.gov.uk/environment/gm/research/epg-rg0216.htm>. pp 1-50.

Rieger, M.A., Lamond, M., Preston, C., Powles, S.B., Roush, R. (2002). Pollen-mediated movement of herbicide resistance between commercial canola fields. *Science* **296**: 2386-2388.

Thompson, C. E., Squire, G., Mackay, G. R., Bradshaw, J. E., Crawford, J., and Ramsay, G. (1999). Regional patterns of gene flow and its consequences for GM oilseed rape. Lutman, P. J. W. eds.

¹⁹ Thompson, C. E., Squire, G., Mackay, G. R., Bradshaw, J. E., Crawford, J., and Ramsay, G. (1999). Regional patterns of gene flow and its consequences for GM oilseed rape. Lutman, P. J. W. eds.

GM plant was derived) of the GM canola under consideration. Then we would compare the groups to see if there are any differences that may arise from the genetic modification. We would expect all other feed stuffs to be identical, and not GM material.

Monsanto's GM RR canola (line GT73) was derived from the parent plant "Westar", so we would expect a trial using feed derived from uncontaminated homozygous GT73 seed, to compare with Westar.

So What Did Monsanto Do?

Raising the seed...

[Except where otherwise referenced, the material for this section comes from MSL#: 12970. Study #: 92-02-30-01: Evaluation of Glyphosate-tolerant Canola Lines from the 1992 Canadian Field Trial, including Attachments #1 and #2.]

For the trout feeding trial Monsanto reportedly used seed from a source which was heterozygous for the GM trait (GT73) (~half-strength). If self-pollinated it would be expected that this seed would grow into plants with either

- a) Two copies of the GM trait genes
- b) One copy of the GM trait gene
- c) No copies of the GM trait genes

These plants were designated to be not sprayed with Roundup, so non-GM and half-strength GM plants would be expected to be flowering within the plot. The final zygosity of the seed produced would depend on the pollination sources.

If pollination was confined to the plot itself, the seed should be a mix of zygotes, on average half-strength GM. However, no pollen barriers were erected.

In the same trial plot area there was a plot of non-GM Westar seed which was to be used as the comparison feed for the trout. It was planted within meters of the GM feeding trial plots in some cases. This meant that the GM plants could be contaminated by the non-GM, and that the control non-GM Westar could be contaminated by the GM plants.

Furthermore, Monsanto required that these GM and non-GM plots be surrounded by a 10m border of the non-GM Westar parent plant, without specifying the distance. At least one border was planted within 1.5m of the heterozygous GM canola plants, another at 2.5m. It is to be deduced that cross-pollination from these parent plants would have resulted in further reduction of the GM component of the final seed.

What is evident is that Monsanto began with a dilute GM crop line, and surrounded the plots with material that would further dilute it. Furthermore, although not reported, it appears certain that the non-GM Westar plot used in the trials would've been GM contaminated. It also appears that this was known and expected by Monsanto. There was late advice to the farmers to apply pollination bags to five of the plants in the Westar plots: "The purpose was to obtain pure Westar control seed that had a minimum chance of having outcrossed with the GTC [Glyphosate Tolerant (GM RR) Canola]."

There was a more profoundly bizarre twist. Strangely another GM canola line (GT200) was in duplicate side-by-side plantings, as close as 0.25m from the heterozygous GT73 line intended for the feeding trials. Contamination would be pronounced and unavoidable. If the GT200 traits were otherwise located on chromosomes, there may have been stacking of traits. They did the same with their homozygous plots... why???

Why would Monsanto intentionally contaminate their lines? [I don't know the answer – I can imagine a range of possibilities but they are pure speculation.]

In 2002 Monsanto went to the US FDA and reported that their GT73 line (the line approved for planting in Australia) 'may be' contaminated with the GT200 line²⁰ ...no bloody wonder. The GT200 line has not been approved for planting in Australia, but it seems a likely contaminant. In telephone conversation with the OGTR I learnt they were not aware of the possibility of contamination.

As if this wasn't enough, Monsanto reported that the planting by plot number had not been consistent across all sites. When the seed from the two lines GT73 and GT200 was combined for trials, it was mixed, invalidating comparison results, as if the expected contamination through cross-pollination was not enough.

Monsanto reported "The outcome was that samples intended to be pure GT200 were, in fact, 53% GT200 and 47% GT73. Similarly, samples that were targeted to be pure GT73 were 53% GT73 and 47% GT200."²¹ How could Monsanto have imagined that their GT200 and GT73 samples would be pure, when they were required to be planted 1.5m apart?? Monsanto had been sufficiently aware of cross-contamination to require bags to be put on non-GM Westar plants some meters from the GM plants to keep the seed pure.

Additionally, these GM plots were not sprayed with Roundup, which means that the seed used in the trout trials didn't contain Roundup residues. This may have given a further positive bias, and does not represent the nature of the material that would be fed to animals in Australia – the point of the crop to farmers is that it can be sprayed with Roundup to eliminate weed competition.

Preparing the meal...

The seed was grown in Canada, and then sent down to Texas for processing. Oil was to be extracted, and residues were to be converted into Canola meal for the trout feeding study.

The study noted (and appeared confused by) further problems.

Attachments #3 and #4 of MLS#12970 Study #92-02-01 describe the seed processing protocols and conduct. After the oil had been finally extracted, the applied hexane could be removed with the application of warm air. Alternatively, "at the option of the sponsor" warm air could be substituted with toasting. The protocol said that steam would be injected until the temperature reached 94-99 degrees C, and the meal would continue to be mixed and heated until the temperature reached 105-114 deg C, then held at that temperature for 20 to 30 minutes.

Attachment #4 said that the meal had been toasted, but when the three samples (intended to be #01 – non-GM Westar, #03 – heterozygous GT200, #04 – heterozygous GT73) were analyzed there were considerable differences. The #04 sample was particularly dry and with low nitrogen solubility (bad for fish). It was noted in the attachment that the steam for sample #04 had only reached 84 deg as opposed to 94-99 deg – would this result in dryness after toasting? The material provided by Monsanto said "Note that the attachments to this final report, describe[d] in its table of contents, have not been included in this attachment. All raw data and a

²⁰ Biotechnology Note to File No. 77 . Hit the 'memo' link for more information. <http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=biolisting> The Biotechnology Note to File for Monsanto's GM RR canola GT73 is No. 20

²¹ MSL#: 12970. Study #: 92-02-30-01: Evaluation of Glyphosate-tolerant Canola Lines from the 1992 Canadian Field Trial

complete final report are archived at Monsanto, St. Louis." We'd have to be very eager to access this data to see what happened, assuming it was honestly reported.

But the upshot... the results for the #04 trials (meant to be the GM canola we are interested in, GT73) suffered disadvantages in feed efficiency and reduction in growth. Monsanto could cover this outcome by saying that the sample was completely mixed with GT200, and that the results were different because of reported toasting differences that can't be reviewed.

Remembering that all of this information is provided by Monsanto, the commercial company of interest, what do we believe?

The contamination of the GM varieties was later acknowledged and poor results for the GM canola (the variety now planted in Australia) were explained away by the authors on the basis of "overcooking" the meal...

"Proximate analysis of each sample prior to formulation into test diets showed a markedly lower nitrogen solubility [...] indicative of differential processing (overcooking) of [the RR canola sample], and may explain differences noted in this study."

"Overcooking" makes sense given the low moisture content reported in the published study – whether it was a result of earlier steam temperature I haven't read enough to comment.

On another matter, 20% of the feed used in the trials was derived from soy. Was this GM soy, capable of masking the results? It was reported neither as GM nor non-GM. This is a common problem faced in reviewing animal trials

The published study went through the motions, carefully describing all the differences noted between the different feeding groups, and then in the discussion said "However, because of a mixing error that occurred prior to the first study, samples of seed labeled GT200 and GT73 were essentially equivalent in composition". That is, the results are meaningless.

The trial was repeated but with far more adverse effects on fish production values. Weight gain was halved, feed efficiency and protein efficiency ratio declined. Death rates weren't high but they tripled, and we have to ask the question, what happened to the feed this time to produce these highly adverse results?

The study did not detail any aspects of seed and meal production for the repeated trial.

The published study said the feeds for the second trial (Westar and GT73) came from the same Canadian field trials, but I don't know where they could find uncontaminated material given the planting methodologies. The soy was replaced with "wheat midds".

In the animal studies to come we will see trial differences explained again on the basis of overcooking of meal prepared 'by Monsanto', described below as "differential processing".

The Chicken Study

Taylor ML, Stanisiewski EP, Riordan SG, Nemeth MA, George B, Hartnell GF (2004) Comparison of broiler performance when fed diets containing roundup ready (Event RT73), nontransgenic control, or commercial canola meal (vol 83, pg 456, 2004). Poultry Science 83:1758 <http://ps.fass.org/cgi/reprint/83/3/456>

Monsanto conducted this study. Monsanto prepared the canola meal for the GM variety and its (reportedly) non-GM counterpart.

Based on their conduct in the trout trials Monsanto could've done anything in the growing of the seed or the preparation of the meal – leave it up to your imagination.

For comparison, Monsanto also brought in six additional commercially produced canola meals.

The Monsanto data we obtained through the OGTR reported that all of these lines were GM contaminated for the Monsanto GM genes being trialled!!²²[p19] Monsanto wrote that it was to be expected because GM canola had been grown in Canada for a few years and naturally there'd be contamination. For all we know these commercial feeds may have been full strength Bayer GM Liberty Link canola, stacked by contamination with Monsanto genes – Monsanto didn't report testing for this.

So we're not really comparing GM vs non-GM feed, but Monsanto prepared feed versus commercially prepared feed. The trial is useless.

The profound initial difference between the non-GM counterpart and the commercially produced meals can be read in the online published study²³. It appears that the non-GM and GM seed or meals had been considerably overcooked, as for the trout study. Moisture levels were very low, probably explaining higher apparent protein and fat levels in the GM and non-GM counterpart varieties prepared by Monsanto.

The different preparation may be able to account for the dramatic difference in deaths between the chickens fed the commercial meal and the chickens fed the Monsanto prepared meals²⁴. The study acknowledged...

“The differences in mortality between commercial reference diets and test and nontransgenic control diets may be attributable to differences in processing at the 2 facilities.”

Monsanto reported in their data that the deaths were “slightly higher than expected”. In fact, female chickens reared on Monsanto prepared feed died at 3x the rate of females fed on commercial feed, and male chickens died at twice the rate.

²² MSL No.:17538; Stanisiewski et al 2001; Monsanto Company, Product Safety Centre, Biotechnology Regulatory Sciences. Sponsor Summary of Report for Study #00-01-43-10; Comparison of Broiler Performance When Fed Diets Containing Roundup Ready (Event RT73), Parental or Commercial Canola Meal

²³ Published study: Table 1, page 3: The moisture rates for the two feed lines provided by Monsanto – indicate they're extremely dry – an example of overcooking reported by Monsanto in respect of its trout study

²⁴ Published study: Table 4, page 5: Mortality rates for the two feed lines provided by Monsanto - published death rates in the days (7-42) birds are about 3x higher in the females, and twice as high in the males.

As a result of the very high number of deaths, the breast weight per pen and the breast weight/feed intake was significantly lower for the Monsanto processed feeds, but these results were not presented in the study - they had to be deduced from the other data, accounting also for gender differences and concomitant body size in the death rates.

The results presented by Monsanto were expressed in terms of the chickens that actually survived and appeared healthy at slaughter time - they did not account for the lost production as a result of the very high number of deaths. This is not a fair presentation for farmers concerned at economic levels.

There were deaths, and there were animals killed due to their unhealthy condition. Animals were also described as having been 'removed'.

We also don't know how this trial may have been rigged to produce the results it did. In the data provided to the OGTR, Monsanto failed to report the details of 83 of the chickens removed from the study!!! They could take out skinny chickens, or fat chickens, and alter results.

As a study on the effect of genetically engineered feed it can't be viewed with any credibility. The difference between the Monsanto produced non-GM feed and the commercially produced non-GM feeds indicates strongly that something was wrong, and that whatever produced this effect may have overridden any GM effects that may have otherwise been observed.

Furthermore, the animals were fed very large amounts of both corn and soy without mention of whether these were GM varieties, containing the same GM genes as the GM RR canola.

This study is nothing more than a compilation of material to create the impression that something has been evaluated, without providing any clear information about their relative efficacy of their feed.

Reading this study, a chicken farmer would best conclude that he/she should not feed his chickens on Monsanto-prepared feed.

It is a good exercise to go through the birds one by one (using a program such as excel) and try to trace their outcomes. The non-reporting becomes evident. Also, use the data in Table 5 to deduce the unstated significant differences. I've done it by hand, and if you'd like to see these excel files I can readily send them.

The Lamb/Sheep Study

K. Stanford¹, J. L. Aalhus², M. E. R. Dugan², G. L. Wallins¹, R. Sharma³, and T. A. McAllister³
;Effects of feeding transgenic canola on apparent digestibility, growth performance and carcass characteristics of lambs; Can. J. Anim. Sci. 2003 83: 299-305; <http://pubs.nrc-cnrc.gc.ca/aic-journals/2003ab/cjas03/jun03/cjas02-056.html>

This study was financially supported by Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, and the Canada/Alberta Livestock Trust. Researchers from three agricultural research institutions in Canada co-authored the study.

Monsanto was acknowledged for providing the GM and non-GM counterpart canola meal for this study. The study used two commercial canola meals for comparison.

Again, as for the chicken study, this meal contained proportionally high amounts of protein and fat, and contained a very high percentage of dry matter in comparison to the commercial feeds. It may have been from the same seed material used for the chicken study, but this can't be determined from the information provided.

There was a small problem with this study. The authors repeatedly wrote that they tested for the "EPSPS" gene in the feed – this is the terminology used to denote the natural plant gene. I suppose they were meaning Monsanto's usual GM gene "CP4 EPSPS", but it was a disconcerting read. The authors may have been out of the loop of this sort of DNA assessment.

There was no information to indicate whether the commercial canola meals were full strength Bayer GM canola meals, for example. Contamination is to be expected.

Again, the lambs fed on the Monsanto-prepared meal had significantly disadvantageous results. The clearest result is that the carcass yield grades were significantly reduced for these groups.

This study did not look at any variables that could be related to human health, but did give a nice description of the study of lamb chops, and part is described here to highlight the irrelevance to human health and safety...

"A 2.5cm chop was cut from the posterior end of the [sheep bit] and the remaining portion was vacuum packaged and held overnight at 4degC . The chop was weighed, placed on absorbent pads in Styrofoam retail steak trays, overwrapped with oxygen-permeable film [...] and held for 2d at 2degC to determine drip loss.

"At 48h post-mortem, the posterior end of the [sheep bit] was trimmed, 48-h pH recorded and two 2.5-cm chops were removed. One chop was exposed to air for a minimum of 20 min before colour was assessed. [...]"

"Both chops were cooked to a final internal temperature of 75degC as measured by a spear-type temperature probe inserted into the mid-point of the chop and monitored [...]. Chops were cooked in groups of eight on an electric grill [...]. Upon removal from the grill, the chops were sealed individually into polyethylene bags, and immediately immersed in an ice/water bath to prevent further cooking [...]"

This is a food production study. It is not a human health safety study.

The pig study

J. L. Aalhus*¹, M. E. R. Dugan¹, K. A. Lien², I. L. Larsen¹, F. Costello¹, D. C. Rolland¹, D. R. Best¹, and R. D. Thacker¹ Effects of feeding glyphosate-tolerant canola meal on swine growth, carcass composition and meat quality. ; J. Anim. Sci. 2003. 81:3267;
<http://jas.fass.org/cgi/content/full/81/12/3267>

A full-text version of this study does not appear to have been written up as a study for peer review, but the authors of the study came from one of the Agriculture and Agri-Food Canada research centres and the University of Alberta, Edmonton Canada.

MADGE has asked the authors for full study detail but has received nothing. We are only able to report from an abstract. The same feed groups applied as for the lamb study, and we expect that the feed provided by Monsanto was identical to that provided for the lambs, and that the commercial feeds were GM contaminated. No data was given for moisture content or protein and fat levels.

As for the chicken and lamb studies there were significant differences between the pigs fed on the commercially prepared canola meals, and those fed on the Monsanto-prepared meals.

"Average daily gains, daily feed intakes, and feed conversion efficiencies were similar when feeding the PAR and RRC diets, but some differences from the COM diets were noted ($P > 0.05$)." The abstract didn't report the direction of difference. As for the lamb study there were differences in the carcass and meat quality evaluations, but didn't say what they were.

This was another food production study.

Five other studies using GM RR Canola

These studies were conducted by researchers at four Canadian agricultural research institutions in various collaborative combinations. One of the studies had three Monsanto staff on the authorship.

The studies were conducted in series, with the general intent being to identify the true fate of GM DNA in animals, and to determine whether it would be taken up by body tissues or by bacteria (and other microflora) in the digestive tract.

The series did not make any findings that the GM DNA had been taken up by digestive microflora, but the final study found that GM DNA was present in digestive tissues in sheep and pigs, and in the liver and kidney of pigs.

Alexander et al (2002)

Alexander TW, Sharma R, Okine EK, Dixon WT, Forster RJ, Stanford K, McAllister TA. Impact of feed processing and mixed ruminal culture on the fate of recombinant EPSP synthase and endogenous canola plant DNA. FEMS Microbiol Lett. 2002 Sep 10;214(2):263-9; http://www.ncbi.nlm.nih.gov/pubmed/12351241?ordinalpos=8&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum

This study looked at what happened to *GM* DNA at various stages of feed processing. It determined that full lengths of one of the new *GM* genes could be found through all stages, from whole seed to processed meal in pellets.

It also looked at how rapidly the *GM* DNA was digested by extracting ruminal fluid from a Jersey steer. *GM* DNA was detected for up to 8 hours for meal and 4 hours for mixed diet.

Further, it found that plant DNA was rapidly degraded upon its release into rumen fluid.

Sharma et al (2004) (abstract only)

Sharma R, Alexander TW, John SJ, Forster RJ, McAllister TA. Relative stability of transgene DNA fragments from *GM* rapeseed in mixed ruminal cultures. Br J Nutr. 2004 May;91(5):673-81. http://www.ncbi.nlm.nih.gov/pubmed/15137918?ordinalpos=7&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum

This study looked at the presence of *GM* DNA in buffered ruminal contents, and looked for evidence that *GM* DNA had been taken up by bacteria.

It found that *GM* DNA persisted in ruminal contents for at least 48 hours depending on feed type, but did not determine that *GM* DNA had been taken up by bacteria over that 48 hour incubation.

Alexander et al (2004)

Alexander TW, Sharma R, Deng MY, Whetsell AJ, Jennings JC, Wang YX, Okine E, Damgaard D, McAllister TA (2004) Use of quantitative real-time and conventional PCR to assess the stability of the cp4 epsps transgene from Roundup Ready (R) canola in the intestinal, ruminal, and fecal contents of sheep. Journal of Biotechnology 112:255-266 http://www.ncbi.nlm.nih.gov/pubmed/15313003?ordinalpos=6&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum

Monsanto had three co-authors on this study.

This study had two purposes: first to examine the stability of DNA in various digestive fluids of sheep, and secondly to assess the stability of one of the *GM* genes during incubation with digesta from the sheep small intestine.

The study found that the digestion of plant material and release of *GM* DNA can occur in the sheep small intestine. It found that free *GM* DNA is degraded more quickly at higher

pH levels. It determined that the rapid degradation of *GM* DNA reduced the likelihood that it would be taken up into the body of sheep.

It is worth noting that the study gratefully acknowledged "The Natural Sciences and Engineering Research Council of Canada (NSERC)-Monsanto industrial scholarship to Trevor W Alexander and the NSERC fellowship to Ranjana Sharma [..]", the two principal researchers in this line of study. Such a scholarship sounds a cautionary warning for the independence of the findings.

Alexander et al (2006)

Alexander TW, Reuter T, Okine E, Sharma R, McAllister TA. Conventional and real-time polymerase chain reaction assessment of the fate of transgenic DNA in sheep fed Roundup Ready rapeseed meal. *Br J Nutr.* 2006 Dec;96(6):997-1005.
http://www.ncbi.nlm.nih.gov/pubmed/17181873?ordinalpos=4&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum

This study specifically focused on quantifying the persistence of *GM* DNA at various points in the sheep digestive tract, using both a forage-based or concentrate-based diet containing *GM* RR canola. The presence of *GM* DNA in blood was also tested.

Whole *GM* genes were detected for up to 13 hours after the last feed of *GM* diet, and *GM* fragments were detected for up to 29 hours in ruminal and digestive fluid. *GM* DNA was not detected in faeces, blood or microbial DNA. *GM* DNA was not amplifiable in ruminal and digestive fluid supernatant fractions.

Sharma et al (2006)

Sharma R, Damgaard D, Alexander TW, Dugan ME, Aalhus JL, Stanford K, McAllister TA. 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
<http://pubs.acs.org/doi/abs/10.1021/jf052459o>

This study looked for the presence of *GM* and non-*GM* DNA in the tissues of sheep and pigs. High copy ordinary plant chloroplast DNA was detected in the esophagus, rumen, abomasums, small intestine and large intestine of the digestive tract tissues of sheep, and in the duodenum and cecum of pigs.

It was also found in the liver and kidney of sheep, and in the liver spleen and kidney of pigs.

Fragments of the low copy *GM* DNA were found in the digestive tract tissues of sheep and pigs previously mentioned. Fragments were also found in the liver and kidney of pigs.

The authors concluded that *GM* DNA may be found wherever non-*GM* DNA may be found in animal tissue, but that its detection depended on the *GM* concentration of the animal feed, the sample size of the tissue being examined, and the sensitivity of the tests and the size of the fragments being sought. This has very wide-ranging implications that are not discussed here.