Food Standards Amendment (Truth in Labelling—Genetically Modified Material) Bill 2010

Questions on Notice

1. **When the American Academy of Environmental Medicine states that several animal studies indicate serious health risks associated with GM food, including infertility, immune problems, accelerated ageing, faulty insulin regulation , and changes in major organs in the gastrointestinal system, you are saying that those studies are flawed?**

   General comments on AAEM

   The American Academy of Environmental Medicine (AAEM), was founded in 1965 as the Society for Clinical Ecology. "Clinical ecologists" are physicians who practice what they call "environmental medicine." Clinical ecology, which is not a recognised medical specialty, relies on the concept that multiple symptoms are caused by hypersensitivity to minute amounts of common foods and chemicals. Clinical ecology is not an official branch of the American Medical Association and at least one practician has been disciplined by a state medical board in the United States for making false claims. The relevant statement of the Texas Medical Board is below

   "On 27 August, 2010, the Board and William James Rea, M.D., entered into a Mediated Agreed Order requiring Dr. Rea to present a revised informed consent form to patients undergoing injections for chemical/environmental sensitivity that states that the injections contain only the "electromagnetic imprint" of the agents in question, the therapy is "not FDA approved," and the therapeutic value of the therapy is disputed. In addition, Dr. Rea shall not start using any formulations that contain any amounts of substances classified as hazardous or carcinogenic by the EPA.[1] "

   This is not to say that the entire organisation lacks expertise merely that it represents one position on the safety of GM crops and that position, like some of its members, are not supported by the majority of the scientific or medical communities.

   It is difficult to conduct a comprehensive rebuttal of the AAEM claims because several are made without a reference to specific studies. CropLife has, however, been able to identify some of the references that have been relied upon and all of these have been discredited.

   In general terms CropLife notes the following quote from FSANZ in 2008

   > "The small group of studies often cited as showing harmful effects due to GM foods have, without exception, been discredited by the weight of mainstream scientific evidence and opinion, including that of the UK Royal Society, and by regulatory agencies around the world.[2]"

   In terms of the specific claims that were identified in the AAEM policy statement CropLife can respond directly to the following claims.

   Infertility claims

   The AAEM claims that infertility is associated with consumption of GM foods. This claim is based on an Austrian study from November 2008 that has subsequently been withdrawn by the Austrian Government.

   The study claimed that some of the mice that were fed with genetically modified maize gave birth to fewer offspring. The media and gene technology critics had interpreted the result as evidence of a reduced fertility caused by GM maize.

   On 26 March 2010, the Austrian Government announced in a meeting of the Standing Committee for the Food Chain and Animal Health at the EU Commission in October 2009 that the scientists

[1] Texas Medical Board (2010) "Medical Board Disciplines 187 Doctors and Issues 88 Licenses". Available at http://www.tmb.state.tx.us/news/press/2010/090210.php

[2] FSANZ (2008) "Chief Scientist response to Judy Carman". Available at http://www.foodstandards.gov.au/consumerinformation/gmfoods/chiefscientistrespon3993.cfm

commissioned to do the study failed to deliver a satisfactory report on this study, especially in respect to the statistical analysis of the data. In addition, the Austrian Ministries that had commissioned the study no longer expected to receive such an evaluation.

Previously both the European Food Safety Authority and some national authorities (including FSANZ) had examined the results of the feeding study and had come to the conclusion that no inferences could be drawn from the report since the data were incomplete and contradictory. In addition, important information necessary for a scientific evaluation of the study was missing. Despite their acceptance at that time, the Austrian government was apparently not able to provide either these data or a statistically correct evaluation

Immune problem claims

Claims around immune dysregulation appear to be based on claims by anti GM author Jeffrey Smith that Australian research into a GM pea at CSIRO noted an abnormal immune reaction in mice that would not normally have been detected.

The GM pea had an additional protein inserted that had some similarities to a minor allergen of peanuts and soybeans. The detection of a small change in the mice's immune system was simply an indication that there may be an allergic response towards the introduced protein. This is part of normal testing by researchers and the claims that this sort of reaction would not normally be detected are nonsense. The immune system of the mice functioned in a completely normal, healthy way.

The development of the pea was discontinued as a result of this finding and this result shows that the regulatory rigour surrounding the development of GM crops in Australia is more than capable of detecting any problems in the early stages of crop development.

Decreased birth weight claims

Claims around reduced birth weight rely on a study by *Ermakova et al* that reported reduced fertility in rats that had been fed GM soy. This study has been discredited because of a number of irregularities including:

- Several other high quality, published studies do not find adverse effects on rat pup survival and development
- Soybeans are widely used for animal feed and farmers haven't reported high death rates when feeding GM soy to animals.
- The materials used for the study are not clearly described and may not be comparable.
- Composition of the feed and isoflavone content were not determined.
- The results, especially control group mortality which is ten times higher than normal, suggest poor animal stewardship.
- Misleading photographic evidence is presented. Photographs of rats purporting to show differences in development are clearly of rats of different ages.
- The design of the study did not follow internationally accepted protocols.

It should also be noted that Ermakova is a publicly outspoken critic of GM crops as evidenced by papers on her website and her active participation in an anti-GM advocacy group.

2. Are you familiar with the studies about GMOs and liver problems; that rats fed GM potatoes had smaller, partially atrophied livers, and that the livers of rats fed GM canola were 12 to 16 per cent heavier?

GM potatoes

The potato study referred to by Senator Xenophon was a study by *Armad Pusztai et al*. On 10 August 1998, Dr Pusztai of the Rowett Research Institute in Aberdeen, Scotland appeared on British television questioning the safety of GM foods. Dr Pusztai revealed his results prior to submitting them to the peer review process which underpins scientific knowledge.

Dr Pusztai's experiments aimed to find out if a type of protein, known as a lectin, was harmful to laboratory rats. At that time, lectins were being investigated as a means of introducing pest resistance in crops. Dr Pusztai's experiments appeared to indicate that rats fed GM potatoes had lowered immune systems and smaller organs than normal rats. These findings suggested that procedures used in gene

technology could make plants harmful. Based on this, Dr Pusztai claimed GM foods could have dangers that were not adequately revealed by testing.

Dr Pusztai claimed his results showed that:

- The rats eating the GM potatoes had smaller livers and brains, larger spleens and had suppressed immune systems

- The rats eating non-GM potatoes and those laced with lectin showed no such side-effects.

The conclusions drawn by Dr Pustzai and supporters were that the lectin itself did not cause the problems. Therefore, they claimed something else in the GM potatoes must have harmed the rats.

Given the controversy raised by Dr Pusztai's comments when he appeared on British television, the experiments were reviewed by four separate, independent bodies - the Royal Society, the House of Commons Science and Technology Committee, the Nuffield Council on Bioethics and the a report for the British Government's Ministerial Group on Biotechnology. Each group raised serious doubts about Dr Pusztai's conclusions due to the lack of proper controls and they found no reason to question the safety of GM foods based on his findings. The House of Commons report is no longer available however the other three reports are at **Attachments 1-3**.

In addition, Dr Pusztai's own research institute has questioned the validity of the results. According to the Director of the Rowett Institute, Phillip James, the potatoes came from one crop not two as claimed by Dr Pusztai.

GM canola

The second study that is referred to here was one of three studies that were presented to regulators by the technology developer for assessing the safety of GM canola oil as a food. The study in question did not actually involve feeding rats canola oil because this is nutritionally insufficient to sustain them. Instead the experiment involved feeding the rats "canola meal" -the portion of the canola crop that remains once oil has been crushed from the seeds. This experiment was compromised by known toxicants that exist in the canola meal and these toxicants are the reason for the increase in liver weight. The following is FSANZ's assessment of this data:

FSANZ points out in the safety assessment of foods derived from GM canola (refer: http://www.foodstandards.gov.au/_srcfiles/A363%20FA.pdf that approval applies only to the oil from glyphosate-tolerant canola. Canola meal is not normally considered to be a human food fraction due to the presence of natural toxicants (e.g. glucosinolates). The feeding studies using canola meal were evaluated to compare levels of major components, and any potential unintended effects.

All rapeseed contains natural toxins (such as glucosinolates in the seed meal, and erucic acid in the oil) which are strictly regulated by canola industry standards to very low levels. Canola oil is a highly processed food in which glucosinolates are not present.

Although liver weights were increased in rats fed GM canola meal, this difference was considered to be due to variation in the degree of processing of the GM and non-GM canola seed used in the second study, leading to differences in the levels of glucosinolates in the meal fraction. Glucosinolates are well known to cause liver enlargement (*Hayes, Principles and Methods of Toxicology, 3rd Edition*). Equally and perhaps more likely, the slight increases in liver weight were due to chance, as there were no other behavioural or physiological differences detected.

FSANZ scientists, the New Zealand Ministry of Health and the New Zealand Institute of Environmental Science and Research, the South Australian Department of Human Services, regulators in Japan, USA, UK and Canada, and members of FSANZ's panel of independent experts were satisfied with this evaluation. **FSANZ concluded that there were no human health and safety concerns in relation to the feeding studies in rats fed on canola meal.**

3. How is 'unintentionally present' defined by your association?

CropLife Australia believes that the term 'unintentionally present' refers to instances where a particular trait is present despite all participants in the supply chain making their best efforts to avoid this happening.

4. How do you advise your members on the issue of due diligence and on the issue of 'unintentionally present'?

CropLife Australia does not provide specific advice to members on the issues surrounding due diligence. The point we are making in our submission is that the Corporations Act already requires company directors to exercise due diligence in ensuring that their company complies with relevant legislation, such as food labelling.

The first obligation of all CropLife members under the CropLife Code of Conduct is to ensure that they are compliant with relevant Australian legislation including the Corporations Act, which is specifically referred to. The CropLife Australia Code of Conduct is at **Attachment 4** and is also available here http://www.croplifeaustralia.org.au/default.asp?V_DOC_ID=2000 .

CropLife was heavily involved in the development of standards and protocols that aimed to minimise the occurrence of unintentionally present GM canola. These standards were developed before GM canola was commercialised in Australia. CropLife worked with many other grain industry partners to develop the Single Vision Statement for GM Canola that included protocols and processes for each stage of the supply chain to minimise the occurrence of accidental presence. A summary of this process is at **Attachment 5** and is available at:
http://www.croplifeaustralia.org.au/files/newsinfo/facts/biotechnology/Principles%20for%20Process%20Management%20of%20Grain%2022%20August%202007.pdf

CropLife Australia's biotechnology members are also bound by CropLife Australia's Product Launch Stewardship Guidelines which require members to:

1. Conduct a market and trade assessment to identify key import markets, including those with functioning regulatory systems, prior to the commercialisation of any new biotechnology product (crop by event) in any country of commercial launch. In that market and trade assessment, consult at an early stage with the value chain for the specific crop. Manage the product's introductions so that choice of production methods (ie. facilitate coexistence) and markets (eg. specialty, identity preservation and global) for that crop are available and preserved.
2. Meet applicable regulatory requirements in key markets prior to commercialisation of a new biotechnology product intended for international commodity trade unless determined otherwise in consultation with the value chain for the crop.
3. Follow generally accepted best seed quality practices designed to prevent adventitious presence of unauthorised products and minimise unintended incidental presence of products authorised in the country of production.
4. Make available prior to commercialisation a reliable detection method or test for use by growers, processors and buyers that enables crop identity verification for intended use.
5. Promptly communicate broadly and in a transparent manner with stakeholders as to further company specific product launch stewardship policies and their implementation.

The full text of this policy is at **Attachment 6** and also available at:
http://www.croplifeaustralia.org.au/default.asp?V_DOC_ID=2234

5. Quantify the costs of segregation at different levels

There is a range of costs that are impacted when thresholds for accidental presence of GM traits are lowered. These include testing, sampling, production practices (e.g. buffer zones) and transport costs.

Segregation costs may vary from country to country and from crop to crop. There have been some studies that have tried to quantify these but crops, country, threshold level and methodology vary considerably. As a result it is not possible to put a precise figure on the costs of segregation at each threshold in an Australian context for all crops.

The available studies show that costs increase dramatically as thresholds are lowered. However, the exact amount of that cost varies depending on the study, the crop and the country in which it was studied.

In most of these studies, only a small number of thresholds have been costed and often these costs relate to only part of the production process. For example, there are several studies that have been performed on the cost of producing certified planting seed that meets different tolerances for GM content. These costs would be incurred at the point of purchasing the seed. However, they exclude all the costs associated with sampling and testing to meet various thresholds from the farm to the fork.

Professor Nick Kalaitzandonakes from the University of Missouri has conducted several of these seed production studies for maize seed in the US. In 2004 Kalaitzandonakes and Magnier analysed the costs of a 1%, 0.5% and 0.3% threshold in corn seed production. They found that "compliance costs, on average, would increase by 9.06% for the 1% threshold, 26.82% for the 0.5% threshold, and 35.29% for the 0.3% threshold". This study is included at **Attachment 7**.

In 2005 Prof. N. Kalaitzandonakes looked at costs of segregating hybrid maize seed in the EU and showed that setting a labelling threshold for GM adventitious presence at 0.5% would increase costs on average by 44% and at a level of 0.3% on average by 54%. Because of smaller seed production fields in the EU compared to the USA, these additional costs are also considerably higher in the EU than for US seed producers (increases of 34% and 42% at labelling thresholds of 0.5% and 0.3% respectively).

As noted previously, these costs only refer to the additional costs of providing non-GM seed to the farmer. They do not include the additional costs in production and in the supply chain after the farmer purchases the seed.

In 2006 ABARE estimated that the costs of producing certified seed would constitute around 43% of the total costs of segregation, so the above costs would more than double when calculated throughout the supply chain. The remaining 57% of costs would include on-farm costs, testing costs and costs of labour in the supply chain.

There have been several studies that have tried to quantify the costs across the entire supply chain. Using an economic model Gruere (2009) found that the costs of segregation decreased by more than 70 per cent when the AP tolerance increased from 0% to 5% in both soybeans and maize across a range of APEC countries. This paper is at **Attachment 8.**

In 2006 ABARE found that segregating to meet the lowest current market thresholds of 0.9% (EU) increased the cost of canola by $14.48/tonne. This represents 4-6% of the usual price of canola. This paper is at **Attachment 9.**