Gene Ethics

Submission for public comment on:

Public Register A1035 – Food derived from Insect-protected Soybean MON87701

Gene Ethics welcomes the opportunity to comment on this application and the FSANZ assessment. We ask FSANZ to favourably consider our comments and recommendations.

Gene Ethics' submission supports:

> Option 1 – Reject the application - *prohibit food from soybean line MON 87701*

Gene Ethics considers that approval of the Application would not meet FSANZ:

> **"3. Objectives**
> In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives, which are set out in section 18 of the FSANZ Act. These are:
> - the protection of public health and safety; and
> - the provision of adequate information relating to food to enable consumers to make informed choices; and
> - the prevention of misleading or deceptive conduct.
>
> In developing and varying standards, FSANZ must also have regard to:
> - the need for standards to be based on risk analysis using the best available scientific evidence;
> - the promotion of consistency between domestic and international food standards;
> - the desirability of an efficient and internationally competitive food industry;
> - the promotion of fair trading in food; and
> - any written policy guidelines formulated by the Ministerial Council"

Safety Assessment

Gene Ethics recommends that:

- the Applicant's data be required to give greater recognition to the novelty of MON87701, a GM organism, and its products. The Applicant offers the weak concept of 'substantial equivalence' as evidence of

safety. But the Biosafety Assessment Tool developed by the Norwegian Centre for Biosafety and the University of Canterbury says: "A human health risk in many jurisdictions, GMO safety assessment is based on the "history of safe use" concept called substantial equivalence (Spök, A., 2007; Millstone, E. et al., 1999). Substantial equivalence is neither a risk assessment framework nor is it the only way to approach an assessment[1]. When it is used as part of the assessment framework, it is a starting point for hazard identification (Kuiper, H. A. et al., 2001)), and should not be used as a conclusive endpoint. That is, differences between a GMO and a comparable organism with a history of safe use are among the potential hazards that should be further investigated. "Biosafety Assessment Tool, GenØk - Centre for Biosafety http://bat.genok.org/bat/, accessed: May 10 2010.

- FSANZ review the narrow focus of its current assessment guidelines[2] for GM foods that rely in large part on the ad hoc and unscientific concept of 'substantial equivalence' between GM and conventional foods. Substantial equivalence is an assumption not a fact and it offers no evidence that GM foods are safe.

- the Application for MON87701 be required to properly investigate safety without employing the concept of substantial equivalence as a conclusive endpoint that can mask significant differences.

- FSANZ acknowledge that the failure to identify hazards in MON87701 does not mean that risks and hazards do not exist.

- FSANZ take into account and re-assess all biologically significant differences in the GM organism MON87701 as application of the 'substantial equivalence' concept was used as a core assessment tool, rather than as a starting point.

- FSANZ require more data as the Applicant's data set fails to consider the full range of uncertainties which may result from the GM process itself (e.g. what effects may be produced by the integration of the transgene at different places in the genome; the effect of the insertion of the transgene on the expression of other genes in the host organism; metabolic effects occurring in the GM organism as a result of transgene expression, etc.)

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1 See BAT figure below for a more complete schematic pathway for assessment.

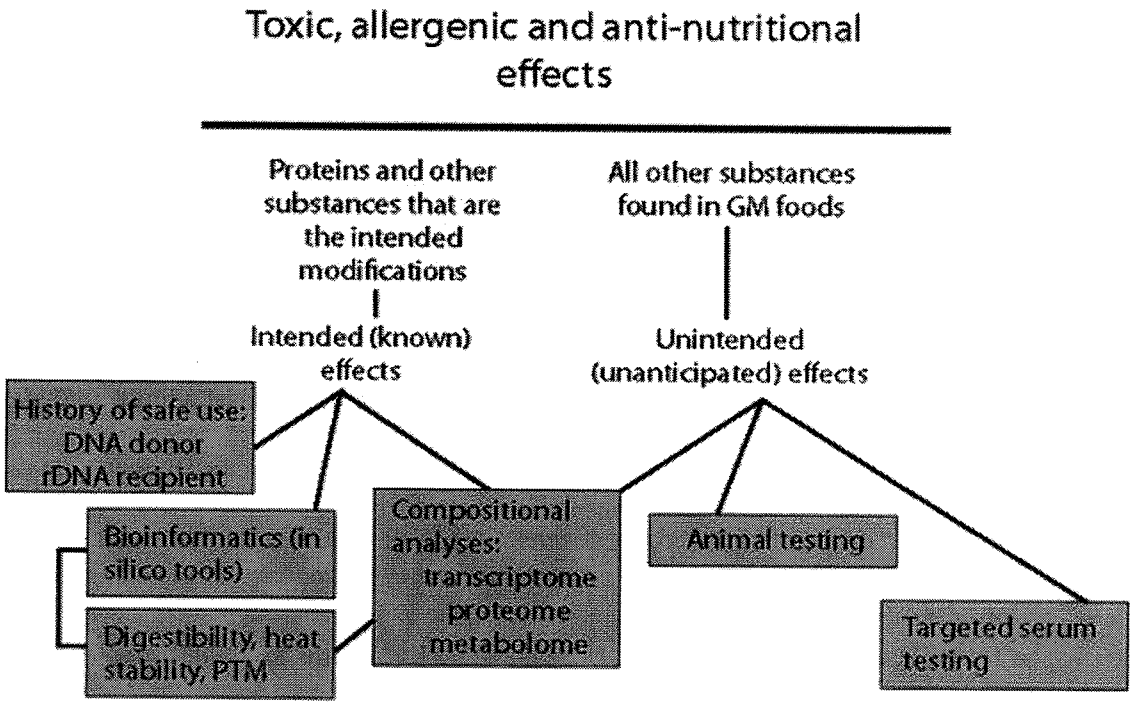
2 "FSANZ (2007). Safety Assessment of Genetically Modified Foods – Guidance Document. http://www.foodstandards.gov.au/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf"

- the data submitted by the applicant be required to show the safety of MON87701 for human consumption. Under the Precautionary Principle, the onus of proof is on the applicant to provide conclusive evidence of safety and efficacy.

- FSANZ not be the first food regulator to approve MON87701 as human food. No other regulatory authority (including those mentioned in FSANZ executive summary: USA, Canada, EU, China, Japan, Korea, etc.) has assessed and approved MON87701. Australia should at least wait until the country where MON87701 may be grown has assessed it as safe.

- FSANZ acknowledge and assess the extensive evidence of harm to experimental animal health - including internal organ malformation, sterility and higher rates of offspring mortality - from numerous animal feeding and related studies using GM soy and other GM crops. FSANZ' criticisms of the research methodologies and data from such research cannot be adequately resolved while FSANZ ignores or rejects this evidence. A valid response would be for FSANZ to require the applicant to confirm or refute the findings by replicating the studies or producing other sound and independent evidence.

- the applicant be required to produce scientific data that conclusively shows the safety and efficacy of MON87701 as a whole food. Testing one or a few constituents cannot provide adequate evidence of safety in the short or long term. A pathway for testing novel GM foods would require:



Schematic of pathway and testing for novel GM foods, modified from (Chao, E. & Krewski, D., 2008), from Biosafety Assessment Tool.

Data submitted by the Applicant is deficient and/or does not cover many of these areas.

- FSANZ exercise extra precaution in its assessments of MON87701 as soybean is an allergenic food. For instance, the assessment of MON87701 does not adequately address the evidence that Bt toxin Cry1Ac can provoke immune responses in mice and humans.[3] FSANZ should require the applicant to submit more evidence on this.

- FSANZ consider the evidence from the Phillipines and India which suggests that GM Bt crops may have adverse health impacts on humans working among the crops. Also, the evidence of harm and death among animals fed GM Bt fodder or grazing GM Bt crops. Human deaths have been reported in the Philippines.[4] The implications of this evidence for the safety of feed from MON87701 must be explored and explained.

- FSANZ acknowledge that a food application for GM Bt Brinjal was recently refused in India on health and safety grounds. FSANZ should

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3 Evidence of hazards of GM Bt crops includes:

1. Ho MW. More illnesses linked to Bt crops. *Science in Society* 2006, 30, 8-10, http://www.i-sis.org.uk/isisnews.php
2. Ho MW. Mass death in sheep grazing on Bt cotton. *Science in Society* 2006, 30, 12-13, http://www.i-sis.org.uk/isisnews.php
3. Bernstein IL, Bernstein JA, Miller M, Tierzieva S, Bernstein DI, Lummus Z, Selgrad MJK, Doerfler DL, Seligy VL. Immune responses in farm workers after exposure to Bacillus thuringiensis pesticides. Environmental Health Perspectives 1999, 107 (7), http://www.ehponline.org/members/1999/107p575-582bernstein/bernstein-full.html
4. Vázquez-Padrón R, Moreno-Fierros L, Neri-Bazan L, de la Riva G and López-Revilla R. Intragastric and intraperitoneal administration of Cry1Ac protoxin from *Bacillus thuringiensis* induces systemic and mucosal antibody responses in mice. *Life Sci.* 1999, 64, 1897-912.
5. Vazquez RI, Moreno-Fierros L, Neri-Bazan L, De La Riva GA and López-Revilla R. Bacillus thuringiensis Cry1Ac protoxin is a potent systemic and mucosal adjuvant. *Scand J Immunol* 1999, 578-84.
6. Ho MW and Burcher S. Cows ate GM maize and died. *Science in Society* 2004, 21, 4-6, http://www.i-sis.org.uk/isisnews.php
7. Ho MW. GM ban long overdue, dozens ill and five deaths in the Philippines. *Science in Society* 2006, 29, 28-29, http://www.i-sis.org.uk/isisnews.php

8. 4 Ho MW. GM ban long overdue, dozens ill and five deaths in the Philippines. *Science in Society* 2006, 29, 28-29, http://www.i-sis.org.uk/isisnews.php

agree that the safety of foods from GM Bt crops in general has not been conclusively proven and that much evidence of adverse effects has not been taken into account.

- evidence of the safety of conventional Bt insecticide organisms not be assumed to imply that MON87701 is also safe. A more precautionary assessment is justified as the GM Bt in GM crops, including MON87701 GM soy, is not identical to naturally occurring Bacillus thuringiensis. The two organisms have different modes of application in the environment, release different quantities of Bt toxin and persist for varying durations. The Bt insecticide in MON87701 and other GM crops is expressed in the GM plant cells which are consumed, whereas Bt organisms are sprayed over the crop in solution as an organic insecticide and the organisms return to background levels before harvest.

- the applicant be required to account for the qualitative and quantitative differences in the nature and use of GM Bt in MON87701, produced for use as food or feed.

- FSANZ redress the lack of evidence that MON87701 is nutritionally equivalent to conventional soy. Statistical compositional comparisons with conventional varieties are inappropriate for assessing GM crops which have novel properties and little or no history of safe use in the human food supply. They allow wide margins of error that do not account for all the biologically significant differences which may occur in GM organisms. The Biosafety Assessment Tool says: "Depending on the threshold of proof: substantial equivalence between the GMO and the isogenic conventional comparator, substantial equivalence between the GMO and an assemblage of ad hoc literature or industry comparisons, or substantial equivalence and assumptions of biological relevance, different people will arrive at different estimates of differences between GMOs and conventional organisms." Biosafety Assessment Tool, GenØk - Centre for Biosafety, http://bat.genok.org/bat/, accessed May 5, 2010. A more complete pathway for nutritional, toxicological and compositional analysis is given in the BAT schema above and FSANZ should apply it to this proposal.

- the studies submitted by the applicant be required to provide conclusive evidence of the nutritional value of MON87701 but the applicant's data is deficient in many areas. FSANZ should require data from nutritional studies that consider MON87701 as a whole food. The Biosafety Assessment Tool says: "Nutritional studies seek to establish that the GMO is safe and wholesome and that it has no increase in anti-nutrients as a result of its modification, intended trait or uses, which may differ from the conventional organism. These studies generally take the form of compositional comparisons to identify any increased or

novel anti-nutrients. Following these tests, the GMO should be tested as a whole food." We support this methodology.

- FSANZ risk assessment also include an evaluation of the safety of MON87701 used as animal feed. The safety of animal products for human consumption that come from animals fed MON87701 should also be assessed.[5] If MON87701 adversely impacts animal health, those who eat the products of these sick animals also incur health hazards. Such secondary effects should be assessed and the results reported.

- FSANZ review its safety assessment guidelines which say: "The application of the comparative approach does not, by itself, constitute a safety assessment. Rather, it is a tool that is used to facilitate the identification of similarities as well as differences (either intended or unintended) in the food. It is these defined differences that then become the focus of further scrutiny. The extent of this further scrutiny will depend on the nature of the identified differences, and could range anywhere from further comparisons with relevant conventional foods to the undertaking of traditional nutritional, toxicological or immunological testing." This approach fails to give proper consideration to the novelty of GM foods, fails to take into account the full scope of uncertainties which may arise as a result of the genetic manipulation process, and relies too heavily on 'substantial equivalence'. For instance, the concept of 'substantial equivalence' in risk assessment should identify all the differences between MON87701 and the closest related comparator as the starting point for hazard identification. The Applicant's data does not identify all the differences between MON87701 and its comparator nor does it fully investigate all the differences. The concept of 'substantial equivalence' is erroneously applied to hide differences.

- FSANZ food safety assessments consider the fitness of applicants to hold licenses including the track record of the applicant for truthfulness and transparency in presenting data. Gene Ethics considers there is sufficient reason to doubt the accuracy of the data provided by the Applicant based on the history of the Applicant's corporate conduct. Evidence that Monsanto has sought to produce and present only favorable evidence includes:

    - Offering bribes to regulators in Health Canada for approval of GM

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5 FSANZ executive summary says: "The safety assessment applied to food from soybean line MON 87701 addresses only food safety and nutritional issues. It therefore does not address: environmental risks related to the environmental release of genetically modified (GM) plants used in food production; the safety of animal feed or animals fed with feed derived from GM plants; or the safety of food derived from the non-GM (conventional) plant."

recombinant bovine growth hormone.

- The former head of Monsanto India recently admitted that they faked data for submission to regulators.
- Found guilty in US courts of bribing Indonesian Government officials to bypass environmental impact assessments.
- Was a major producer of Agent Orange and has not been accountable for dioxin induced health effects on Vietnamese.
- Consistently rates lowest on consumer surveys of company trustworthiness.
- Recent Scientific American and Nature Biotechnology editorials which acknowledge that GM companies are failing to cooperate with independent scientific studies and withholding negative evidence.

Labelling

- Exemptions under Standard 1.5.2 mean that many GM foods and ingredients derived from MON87701 would not be labelled in Australia. This is unacceptable as it does not meet FSANZ legislated primary objectives for:

  "• the protection of public health and safety; and
  • the provision of adequate information relating to food to enable consumers to make informed choices; and
  • the prevention of misleading or deceptive conduct."

Impact of regulatory options

Gene Ethics asks FSANZ to amend its assessment and adopt Option 1 because:

- WTO is not the only international legal framework to considers trade in GMOs. The FSANZ assessment of impact on regulatory options considers only the WTO response and overstates the probable impact of adopting Option 1.

- FSANZ asserts that failing to grant approval to MON87701 may trigger a WTO challenge, but this is not supported by any evidence.

- As WTO is concerned with trade policy only, it is not the appropriate forum for judging the safety of GM foods.

- An application for Bt Brinjal in India was recently refused on health and safety grounds and this does not appear to have triggered any WTO response.

- There is sufficient scientific evidence of safety concerns with MON87701 that rejecting the application would not pose a threat of WTO challenge. This is particularly so as no other national food authority has yet approved MON87701, so no precedent exists.

- The Cartagena Protocol on Biosafety is the international law which governs trade and transboundary movement of GMOs based on the Precautionary Principle and this should also be considered in FSANZ assessments.

- As a signatory to the UN Convention on Biological Diversity, Australia has an obligation to cooperate in the adoption of Protocols to the Convention, including the Biosafety Protocol.

- Codex deliberations on the labelling and safety of GM foods have not been concluded.

Assessing the application

Gene Ethics seeks FSANZ agreement that:

- FSANZ cost benefit analysis is limited and does not fully consider the interests of all stakeholders or all industrial sectors, including impacts on conventional non-GM food producers or the organic sector.

- The threat of a WTO challenge is overstated. WTO is not only international legal standard to be considered – e.g. Biosafety Protocol and Codex as the WTO is not the final arbiter of GM food safety questions.

- Disapproving MON87701 would be unlikely to have a significant impact on trade and would be consistent with Australia and New Zealand's WTO obligations.

- Exemptions under Standard 1.5.2 mean that most foods containing MON87701 would not be labelled as GM and this is unacceptable to the majority of shoppers who want precaution exercised on food safety.

- The comparison of options argument is confused and illogical. For instance, FSANZ argues that: "Option 1 would also offer little benefit to consumers wishing to avoid GM foods, as approval of MON 87701 soybean by other countries could limit supplementation of the Australian and New Zealand market with imported soybean products." But this argument implies that Australian and NZ shoppers who seek GM-free foods would be denied benefit if processed soy, containing MON87701, were not imported. This is insupportable.

- There is a lack of technological justification for MON87701. The failure of GM Bt crops to perform in the field and of creating new farm management problems as minor insect pests fill empty ecological niches vacated by Lepidoptera suggests MON87701 may not fulfill the proposed pest protection function and may actually increase pest and disease vulnerabilities leading to lower overall yields. http://news.yahoo.com/s/nm/20100513/sc_nm/us_pesticide_china_3 and **http://www.csiro.au/science/ps8d.html** FSANZ cost benefit analyses, even if primarily concerned with overall trade figures, should include this evidence as approving MON87701 may lead to overall losses in global soybean harvests and availability of soybean products on the market.

- FSANZ acknowledge that little benefit other than spread of Monsanto patented genes is offered to anyone by Option 2.

Conclusion:

Based on the above points, Gene Ethics supports Option 1.

Option 1 – Reject the application - *prohibit food from soybean line MON 87701*

Seamons, Colleen

From: Gene Ethics [info@geneethics.org]
Sent: Wednesday, 19 May 2010 6:09 PM
To: submissions
Subject: Gene Ethics submission on MON87701 attached
Attachments: Sub MON87701 Gene Ethics.pdf

Categories: Purple Category

Gene Ethics submission on MON87701 attached

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THINK, CARE, ACT!

Seamons, Colleen

From: Victoria McKenzie-McHarg [victoria.mckenzie-mcharg@environmentvictoria.org.au]
Sent: Wednesday, 19 May 2010 6:10 PM
To: submissions
Subject: Submission - Gene Ethics re: MON 87701
Attachments: Sub MON87701 Gene Ethics.pdf

To whom it may concern,

Please accept this submission on behalf of Bob Phelps of Gene Ethics, whose email is currently down.

Kind regards,

Victoria McKenzie-McHarg
Safe Climate and Sustainable Transport Campaigner
Environment Victoria

I believe that by working together we can achieve a safe climate future. Are you in?

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