ENSSER Press Release 2012-02

ENSSER calls for scientific debate of potential health risks of GM wheat instead of *ad hominem* attacks on researchers

19 Sep 2012 - On 11 September 2012, the Science Media Centre (SMC) published response comments (by Prof. Rick Roush, Assoc. Prof. Peter Dearden, Prof. Peter Langridge and Dr. Ian Edwards) in reply to expert scientific opinions about the safety of GM wheat varieties that have been developed by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) of Australia. The expert opinions were written by three risk assessment researchers, molecular biologist Prof. Jack Heinemann of Canterbury University (New Zealand), biochemist and epidemiologist Assoc. Prof. Judy Carman of Flinders University (Australia), and molecular geneticist Dr. Michael Antoniou of Kings College London (UK). The expert opinions were written in the form of reports and were prepared at the request of the Safe Food Institute of Australia, and communicated by the associated Safe Food Foundation.

After reviewing the response comments, ENSSER is disappointed by the Science Media Centre's decision to post personal attacks by the commentators on the authors of the original reports, rather than engage in a scientific debate that might have been useful to journalists, its stated audience.

ENSSER encourages the three commentators posting to the Australian SMC website to take future opportunities to address the science rather than use these platforms to engage in *ad hominem* argumentation. The CSIRO, the Australian regulator (the OGTR), and each of these commentators could, and still can, put forth their own risk assessments to the public at any time. This is what we would have expected if the SMC were intending to provide clarity to the media.

In their post to the SMC, the commentators challenge the reports produced by Carman and Heinemann based on normative judgements, unsubstantiated assumptions, an apparently poor understanding risk assessment processes, and undignified name-calling.

Roush and Langridge begin their comments with an attempt to discredit the scientists by calling them "anti-GM campaigners" and "ideologically opposed to GM crops". Roush accuses the scientists of "deliberately bypass[ing] independent scientific assessment" and of practising "anti-GM so-called 'science'", while Edwards accuses them of "grossly premature alarmism". Langridge claims that the authors of the expert opinions "studiously ignore[d] the majority of the scientific literature and data". He further accuses them of deliberately avoiding "the normal process of peer review" and seeking "the appearance of credibility" for "scientifically flawed articles" by putting out a statement by someone with "no real knowledge" of the relevant science and pretending it is "proper science". In other words, Langridge is accusing the authors of perpetrating a kind of scientific fraud. None of these claims can be substantiated, and the commentators do nothing to substantiate them.

Roush and Dearden call Heinemann's report 'speculative'. All risk assessments are speculative because they are performed before the release of the product, whether for a field trial, for animal or human testing, or for a full release. The process requires considering exposure pathways that would exist, adverse effects that could arise, and hypotheses about how to detect any adverse effect if it were to occur and finally to determine if the effect was caused by the genetic modification and how this would be detected. Only after such experimentation is completed would the assessment not be speculative, but then there would be no point to risk assessment!

And we note that when CSIRO in its response says, "High amylose wheat has increased levels of resistant starch, which could have positive benefits for bowel health and people with diabetes" [emphasis added], this is also 'speculative'.

Roush claims erroneously that the authors "bypassed independent scientific assessment." when they did not. Like many government and other reports, they had their findings critically reviewed by fellow scientists (in addition to Dr. Antoniou). They did not send their report to a journal in this instance or seek blind review. However, neither has Roush for his claims (made to ABC radio that the "likelihood that this would happen in humans is very very small"). This conclusion is the outcome of a risk assessment and therefore, by Roush's standard, should have been subjected to "independent scientific assessment". At this time, we are not aware of any blind peer-reviewed journal articles that demonstrate the absence of the potential adverse effects outlined by Drs. Heinemann and Carman, who have publicly requested the evidence. Nor have we seen any blind peer-review of the Australian regulator's risk assessment.

Langridge accuses the report authors of ignoring "the majority of the scientific literature and data" on the safety of GM crops. Is Langridge aware that proper risk assessment is performed on a case-by-case basis? The safety of this particular form of GM wheat cannot be extrapolated from risk assessments of other kinds of plants, other kinds of modifications and modifications for other intended purposes, nor could the OGTR accept such an extrapolation.

Meanwhile, industry representative Edwards quizzically imposes an expiration date on risk assessments. If a risk was not raised at one time, he seems to believe that it cannot be raised later, even if it is a valid risk. We are not aware of any competent authority that would exclude new information at any time. Contrary to Edwards' highly personal views, CSIRO says 'the claims [by Heinemann, Carman and Antoniou] will be considered by CSIRO and the regulatory bodies in the context of all other relevant research in this area.' This is what the report authors were seeking and ENSSER welcomes that response by CSIRO.

ENSSER believes that the public, and science, are done a disservice when debate is reduced to *ad hominem* attack. Further, we believe that both science and the public can be harmed if research is impeded by the 'chilling effect' of such attacks. The public is entitled to a full and informed debate; scientific disagreement should result in further research, not dismissal through personal attack. Drs. Antoniou, Carman and Heinemann have engaged in proper scientific debate. Their expert opinions are based on evidence; their methodology, assumptions, reasoning and data have been provided for all to evaluate. SMC and other such outlets as well as fellow scientists should ensure that responses to their work do the same.

Contact:
Dr. Angelika Hilbeck, ETH Zürich, (E) angelika.hilbeck@env.ethz.ch
Dr. Hartmut Meyer, ENSSER, (E) hmeyer@ensser.org
more information on this case: http://www.ensser.org/democratising-science-decision-making/attacks-via-smc/

ANNEX: Setting the record straight

The Safe Food Institute had requested from Drs. Carman and Heinemann reports evaluating the risk assessment of GM wheat being developed in Australia by the Commonwealth Scientific and Industrial Research Organisation (CSIRO). The wheat is genetically modified using new dsRNA-mediated silencing; the OGTR has given CSIRO approval for field testing and a human feeding study. The Safe Food Institute then asked Dr. Antoniou, among others, to serve as an expert external reviewer of the reports. Dr. Antoniou provided his own conclusions and summary.

Carman and Heinemann are experts in their respective scientific fields and in biotechnology risk assessment. Assoc. Prof. Carman has expertise in animal and human biochemistry, nutrition and infectious diseases. Her work in epidemiology and risk assessment requires her understand how food consumption can affect the health of animals and humans. Prof. Heinemann has expertise in genetics and molecular biology, with an emphasis in infectious genetic elements and horizontal gene transfer. Both scientists have been actively involved in GMO risk assessment for over a decade. In their reports they give their recommendations for a robust sequence of experiments to address plausible potential hazards of the novel food. Proper risk assessment involves identifying potential hazards followed by constructing, where possible, specific and testable hypotheses for how these hazards might arise and how they would be detected.

Prof. Heinemann first constructed an exposure analysis. He asked: How could humans or animals come into contact with the dsRNAs uniquely produced in the GM wheat? The obvious way is through ingestion or inhalation of flour. Then he provided an extensive analysis of peer-reviewed scientific research that demonstrates unequivocally that dsRNA is sufficiently stable to be able to pass through food to humans and animals; it resists digestion, low pH and cooking temperatures.

Having established a scientifically plausible exposure pathway, he then hypothesised how the dsRNA produced by the wheat could cause an adverse effect. The most obvious means would be by doing in the human or animal what it is intended to do in the wheat, and cause gene silencing. He then provided an extensive analysis of peer-reviewed literature that demonstrates unequivocally that ingested dsRNAs either directly, or through amplification of secondary dsRNAs, silence genes in ingesting animals and human tissue culture cells.

A prediction of Prof. Heinemann's hypothesis is that the dsRNA would have to have sequence similarity to human genes in order to cause gene silencing. RNA is composed of nucleotides of mainly four types: A, G, U, C (and sometimes I). These nucleotides can form base-pairs when align and bond with their complementary nucleotides, in the same way as double-stranded DNA. When RNA does this, it is called double-stranded (ds) RNA. He sourced a sequence of the gene targeted for silencing in the wheat, called the SEI gene from *Aegilops tauschii* (a donor of one of the genomes in the multi genome wheat), as the sequence was deposited by the CSIRO on a public database. He found matches between short stretches of the wheat SEI gene and a similar human gene called GBE, and short matches to many other human genes.

For silencing, overall similarity between genes is not important. What is important is the concentration of similarity over a very short stretch of bases pairs in a sequence. The most potent dsRNA for causing silencing is about 21 nucleotides long and is a perfect match to a target, but as few as 7 contiguous base matches can be enough to cause silencing. Prof. Heinemann found too many potential targets to list them individually. So he published the list as Appendix 2 to his report.

Prof. Heinemann thus drew the conclusions that:
1. Exposure to the genetically engineered dsRNA molecules was likely;
2. Uptake was probable; and
3. Unintended silencing of human and animal genes was possible.

In light of his findings, Prof. Heinemann produced a list of 5 essential studies for risk assessment. At no time did he say that the CSIRO product would cause diseases or adverse effects. He did, however, ask for assurance from the Australian regulator and the CSIRO that this risk scenario had been excluded through proper scientific experimentation.

Dr. Carman considered that the most likely gene to be silenced in animals and people would be a similar gene to the one designed to be silenced in the GM wheat varieties. She therefore concentrated her risk assessment on the effects of silencing that gene. She determined that the GM wheat varieties were designed to silence a branching enzyme in the wheat plant that changed the type of carbohydrate that was stored in the plant. She used widely-available sources to determine that a silencing of the equivalent gene in animals and people could cause serious ill-health by changing the way carbohydrate is stored in the body, from a highly branched, soluble form of glycogen to an insoluble form of glycogen with far fewer branches. She further found that some people already suffer from this condition and provided information that severely affected children usually die from the condition.

She then reviewed the animal and human testing suggested by the CSIRO. She found evidence that testing was being conducted to determine if the wheat varieties produced the hoped-for beneficial effects on health but did not find any evidence that any potential adverse effects were being assessed. In fact, she found that the regulator (the OGTR) had determined that "the potential for increased weediness, allergenicity or toxicity ... is not an identified risk and will not be assessed further".

At no time did she say that the CSIRO product would cause a disease or adverse effects. She did, however, provide a list of additional safety assessments on animals and humans that she recommended be done in order to properly investigate possible adverse effects, and she recommended that these be done before the GM wheat varieties entered the animal feed and human food supplies.

Despite their protestations, neither Roush, Langridge, Edwards nor Dearden have offered evidence that these wheat varieties are safe to eat. However, Roush, Langridge and Edwards liberally resort to *ad hominem* attack and speculation on the report authors' motives; speculation for which they have only themselves as sources. None of them provides references to peer-reviewed literature that proves the GM wheat was safety tested on animals before its intended use in a human feeding trial. Such an evidence-based safety assessment is central to a scientific assessment of potential risks.

None of the commentary presented by SMC addresses these issues. None of these commentators provided evidence to prove, or even suggest, that the dsRNA molecules do not transmit to humans or other animals, or that the dsRNA molecules in this GM wheat won't, given the findings that similar plant derived molecules do just that. None of them provided references to peer-reviewed literature that proves the GM wheat was safety tested on animals before its intended use in a human feeding trial. Instead, Roush, Langridge and Edwards liberally resort to *ad hominem* attack and speculation on the report authors' motives; speculation for which they have only themselves as sources.