Testimony on HB 4100 – House Rules Committee - Feb. 12, 2014

Rick North

We have a right to know what's in our food and I urge you to vote for HB 4100 to support GMO labeling.

People have many different reasons to want to know if their food is genetically engineered – religious, nutrition-related and environmental, to cite a few.

The main reason I want to see labeling is human health. GMO's have simply not been demonstrated safe. From 2003 to 2011, before I retired, GMO's were my focus as project director of the Oregon Physicians for Social Responsibility's Campaign for Safe Food. I've spent literally thousands of hours studying the science, carefully examining the arguments of both sides.

Here's what I found out – all a matter of public record:

The FDA doesn't do any safety testing of GMO crops nor do they require any independent testing. The only testing done is by the same corporations developing the crops that stand to profit by their sale. The FDA virtually always accepts their word.

This isn't meaningful regulation – this is a built-in conflict of interest and a rubber stamp.

There isn't 100% proof that GMO crops are inflicting disease on humans, but for decades there have been disturbing data cited in numerous peer-reviewed, quality studies. These need to be heeded and further tested, not ignored or suppressed.

Along those lines, I want to put to rest a myth that there's a "consensus" that GMO crops are the same as conventional foods and safe for human health. This is simply not true. When GMO's first came up for review by the FDA, this is the 1992 statement from the FDA scientific compliance officer: **"The processes of genetic engineering and traditional breeding are different, and according to the technical experts in the agency, they lead to different risks."** (Document attached) The FDA scientists were over-ruled by the political administrators and GMO's were declared "substantially equivalent" to conventional crops.

This is the 2009 statement from 26 leading scientists to the EPA protesting the biotech industry's refusal to allow independent testing on most GMO crops: **"Technology/stewardship agreements required for the purchase of genetically modified seed explicitly prohibit research . . . no truly independent research can be legally conducted on many critical questions . . ."** (Document attached)

Finally, a statement from last year by an international group of 93 scientists, academics and physicians: **"Claims of there being a scientific consensus that genetically modified organisms (GMO's) are safe are misleading and misrepresentative with potentially dangerous effect on regulation of GMO's."** (Document attached)

To put this in perspective, there's as much of a scientific consensus on the safety of GMO's as there is a legislative consensus on the advisability of the CRC.

For now, the most we can do is label GMO's so consumers can make an informed choice. We have the right to know what's in our food and if the government doesn't require labeling, we should have the right to vote on it. Please support HB 4100.

Thank you.

Rick North – Retired Project Director, Oregon Physicians for Social Responsibility Campaign For Safe Food

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Scientists' Statement to U.S. EPA

EPA
Public Submission : EPA-HQ-OPP-2008-0826-0043
Docket: EPA-HQ-OPP-2008-0836
2/9/09

The following statement has been submitted by 26 leading corn insect scientists working at public research institutions located in 16 corn producing states. All of the scientists have been active participants of the Regional Research Projects NCCC-46 "Development, Optimization, and Delivery of Management Strategies for Corn Rootworms and Other Below-ground Insect Pests of Maize" and/or related projects with corn insect pests. The statement may be applicable to all EPA decisions on PIPs, not just for the current SAP. It should not be interpreted that the actions and opinions of these 26 scientists represent those of the entire group of scientists participating in NCCC-46. The names of the scientists have been withheld from the public docket because virtually all of us require cooperation from industry at some level to conduct our research.

Statement:

"Technology/stewardship agreements required for the purchase of genetically modified seed explicitly prohibit research. These agreements inhibit public scientists from pursuing their mandated role on behalf of the public good unless the research is approved by industry. As a result of restricted access, no truly independent research can be legally conducted on many critical questions regarding the technology, its performance, its management implications, IRM, and its interactions with insect biology. Consequently, data flowing to an EPA Scientific Advisory Panel from the public sector is unduly limited."

Jim -

Here are my comments on the Federal Register document "Statement of Policy: Foods from Genetically Modified Plants".

1. What is the objective of this policy statement? I see the following possibilities, based on what is in the document:

   a. To respond to numerous requests to the agency to clarify our position with respect to the use of the new techniques of biotechnology, and specifically genetic engineering, to produce new cultivars of food crops.
   b. To prepare a comprehensive agency policy with respect to new cultivars of food crops - regardless of whether these food crops are prepared by new or traditional methods.

   The current document (particularly the section on scientific issues and the appendix) is very schizophrenic in regard to the objective. Some of this has been provoked by conflicting comments from multiple sources on previous drafts. Some advice has been "the recommended actions should be the same for cultivars developed by new and traditional methods, because it is the product and not the process that is regulated". Other advice has been "Do you realize that you are proposing regulations for an entire industry that has previously been virtually unregulated and has a history of safety" (i.e., traditional plant breeding).

   Therefore, perhaps the relevant question is not only what the objective of the document as a whole is, but what the objective of the Appendix is. Should this in fact be "Points to Consider" for new methods of biotechnology, since guidance has been requested, and guidance on traditional breeding has already been given (GRAS symposium, CFR)? Can the objective of the Appendix be "A" even if the objective of the policy statement is "B"?

   The June 1986 Coordinated Framework does not seem to be so concerned with traditional methods and makes no apologies for discussing only biotechnology. It is very concerned with making it clear that no new legislation is needed. It notes that the framework seeks to distinguish those organisms that need review and those that do not. So why can't the current appendix deal only with new biotechnology? Why try to make it appear that we are discussing all modified crops?

2. I believe that there are at least two situations relative to this document in which it is trying to fit a square peg into a round hole. The first square peg in a round hole is that the document is trying to force an ultimate conclusion that

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there is no difference between foods modified by genetic engineering and foods modified by traditional breeding practices. This is because of the mandate to regulate the product, not the process.

a. The processes of genetic engineering and traditional breeding are different, and according to the technical experts in the agency, they lead to different risks. There is no data that addresses the relative magnitude of the risks - for all we know, the risks may be lower for genetically engineered foods than for foods produced by traditional breeding. But the acknowledgement that the risks are different is lost in the attempt to hold to the doctrine that the product and not the process is regulated.

b. I don't see how the acknowledgement of the fact that the risks are different compromises the position that it is the product that is regulated. The "Points to Consider" for products of genetic engineering must be different than the "Points to Consider" for products of traditional breeding - how can you expect a traditional breeder to have the most basic molecular data (e.g. DNA sequence of the inserted material) when he has no idea of the molecular identity of the genetic material being introduced? Are we to insinuate that practitioners of genetic engineering do not need to adhere to the most basic level of good laboratory techniques simply because the traditional breeding community cannot also provide that data?

3. The second square peg in a round hole is that the approach of at least part of the document is to use a scientific analysis of the issues involved to develop the policy statement.

a. In the first place, are we asking the scientific experts to generate the basis for this policy statement in the absence of any data? It's no wonder that there are so many different opinions - it is an exercise in hypotheses forced on individuals whose jobs and training ordinarily deal with facts.

b. In the second place, I don't think that the scientific analysis as presented is complete. The scientific issues section of the document talks of the "possibility of unintended, accidental changes in genetically engineered plants" but I believe that in most cases the word "risk" is avoided. This is probably at least partly due to the fact that there is no data that could quantify risk. But if the scientific issues section of the document deals totally in hypotheses about "possibilities", why does it not address the fact that multiple events would have to

occur in order for the "possibility of unintended, accidental changes in genetically engineered plants" to result in a danger to the public health. Surely the following series of events must all occur in order to present a danger to the public health: (1) The accidental change must activate a pathway for production of a toxin that was unanticipated, or for which there is no suitable analytical method. (2) This unanticipated toxin must be expressed at a high enough level to exert an effect. (3) This toxin must have serious adverse consequences to humans and/or animals that consume it. (4) The presence of this dangerous unanticipated toxin in amounts sufficient to cause a public health problem must not manifest itself in any other way, so that the first and only clue will be the "body count", so to speak.

c. I wonder if part of the problems associated with this approach - using scientific issues to set the stage for the policy statement - are due to the fact that the scope of technical experts assigned to the project did not include any whose usual job is risk analysis. This does not eliminate the problem with a lack of data, but if the molecular biology, chemistry, and toxicology experts are being forced to deal with hypotheses rather than data, why not the risk analysis experts?

4. Are there any alternatives to toxicology testing that could tip the scales to a level where the modified food can meet a safety standard of reasonable of no harm? My impression is that the limitation of the number of insertion sites to one is not sufficient - what does that actually tell you about safety? Could a recommendation that any new cultivars that are produced by genetic engineering only be used (at least for the present) after they have been crossed by traditional breeding into an established cultivar take us over the edge to where no tox testing is necessary? Is that what we expect the plant breeding community to be doing anyway? If so, then such a suggestion is not a burden.

5. If we don't get specific and substantial input from CVM on animal feed, should the objective be reduced to human food?

6. This is a minor comment in relation to the overall problems in the document, but there needs to be a decision as to whether we use one phrase exclusively to refer to certain issues/topics/procedures (i.e. to promote clarity), or if we use multiple terms to liven the document up. E.g. the document tends to use the phrase "new methods of biotechnology" in its entirety when applicable; but the document uses "traditional breeding practices", "conventional plant breeding", "classical plant breeding",

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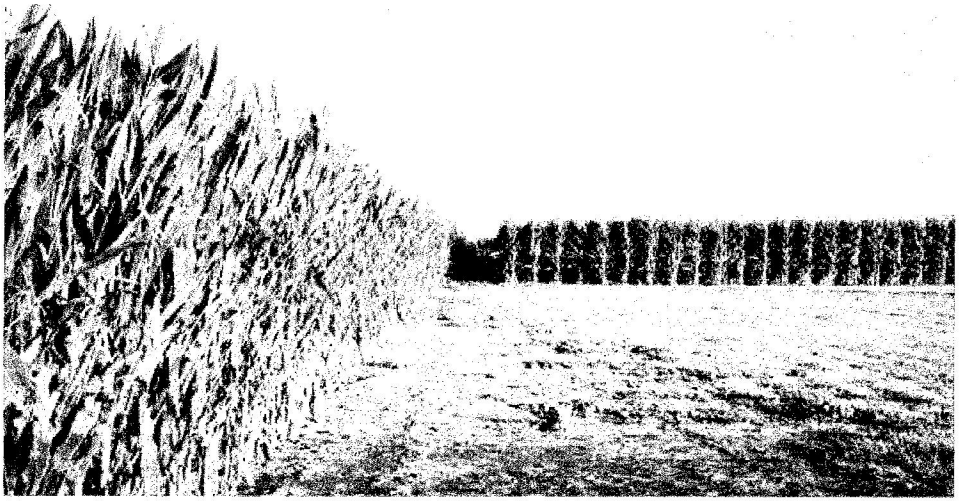

Piotr Malecki / Panos

Speed read

Scientists from around the world challenge claims of GMO food safety

Closing off scientific debate could encourage complacency and poor regulation

Yet others say the group failed to provide enough evidence for its strong claims

[RIO DE JANEIRO] Claims of there being a scientific consensus that genetically modified organisms (GMOs) are safe are misleading and misrepresentative with potentially dangerous effect on regulation of GMOs, says a group of scientists.

The statement was signed last week (21 October) by an international group of 93 scientists, academics and physicians, gathered under the umbrella of the European Network of Scientists for Social and Environmental Responsibility, a non-profit association.

Based on scientific articles and reviews that show contradictory data on the safety of GMOs to human health and the environment, they argue that claims of there being a consensus that GMOs are safe, presented by "GM seed developers and some scientists, commentators, and journalists", is "misleading and misrepresents the currently available scientific evidence and the broad diversity of opinion among scientists on this issue".

It could also encourage "a climate of complacency that could lead to a lack of regulatory and scientific rigour and appropriate caution, potentially endangering the health of humans, animals, and the environment".

Scientific research on GMO safety "has raised more questions than it has currently answered", they say, with results that are "nuanced, complex, often contradictory or inconclusive, confounded by researchers' choices, assumptions, and funding sources".

These decisions on the introduction of GM crops and food must involve wider society, they say, and not just "a narrow scientific debate and the currently unresolved biosafety research agendas".

"They should, however, be supported by strong scientific evidence on the long-term safety of GM crops and foods for human and animal health and the environment, obtained in a manner that is honest, ethical, rigorous, independent, transparent, and sufficiently diversified to compensate for bias," the statement concludes.

"We are concerned about decisions supported by simplified studies, produced by interested companies."

Leonardo Melgarejo, Ministry of Agrarian Development, Brazil

Brazilian agronomist Leonardo Melgarejo, one of the statement's signatories, says the group is worried about the worldwide increase of uncritical thinking and disregard for contradictory arguments over the safety of GMOs and it fears the impact this may have on regulation of GM crops and food.

"We are concerned about decisions supported by simplified studies, produced by interested companies, where you cannot access the raw data, and with the great neglect [shown] to independent publications when these contradict arguments conveyed in marketing campaigns," says Melgarejo, who works for the Ministry of Agrarian Development in Brazil, one of the biggest GM crop producers in the world.

The authors of the statement claim that the lack of epidemiological studies investigating potential effects of GM food on human health makes it impossible to demonstrate the lack of harm.

"We need more detailed and long-term studies," says Melgarejo. He believes the statement could help to reposition the debate and decisions related to GMOs.

But Francisco Aragão, an agronomist at the Brazilian Agricultural Research Corporation (Embrapa), disagrees with the content of the statement and doubts it will have much effect on GMO policy decisions.

"Most scientists believe the biosafety protocols in which the regulatory agencies of organised countries rely on are rigorous — sometimes excessively rigorous, I would say — and feature robust data on the safety of the products tested. This is a consensus," says Aragão.

In his view, both the scientific literature and practice — GM products are already widely planted and consumed by the world's population — confirm the safety of GMOs.

Although Aragão welcomes the discussion over technology, he thinks that, in this case, the data presented by the group are not reliable enough to influence how GMOs are dealt with.

"Decisions can be reviewed at any time, provided there is a really strong fact. As we say, to make strong statements, you must have strong data In this case, the claims are strong, but the data do not follow."

Link to full statement

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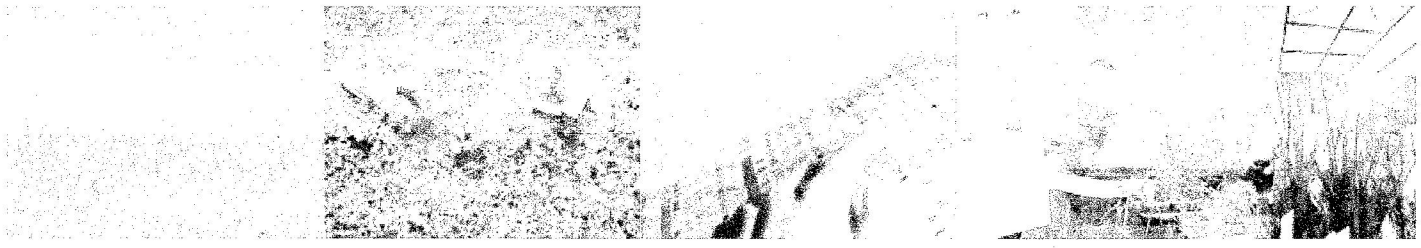

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Carla Almeida