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PUBLIC ACCESS TO INFORMATION, WITH SPECIAL REFERENCE TO MON863

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Affiliation: GM Free Cymru is a voluntary organization (NGO) based in West Wales. It arose from a powerful grass-roots movement which prevented the planting of two trial crops of Chardon LL maize in Pembrokeshire in 2001, during the UK's FSE programme. Since then it has worked closely with other NGOs and consumer groups to keep Wales GM Free, with the broad approval and cooperation of the Welsh Assembly Government. There is no formal membership structure, but the organization has thousands of supporters across Wales. Its affairs are managed by a liaison group which includes organic farmers, scientists, and other concerned citizens. It is funded entirely through voluntary contributions and has no political affiliations.

Introduction

Since it was formed five years ago GM Free Cymru has been intensely frustrated by the secrecy, evasions and obfuscations of the regulatory authorities (including the EFSA) in the face of straightforward requests for information that should be in the public domain. We became aware in 2004 and 2005 that GeneWatch and other NGOs had been trying to obtain access to the dossiers for applications being made under the new GM food and feed regulations (EC No. 1829/2003). In the past, we were told, NGOs had been able to obtain most of the dossiers for applications under the Deliberate Release Directive (2001/18/EC) but had never been able to obtain the applications made under the Novel Food Regulations (EC No. 258/97).

On checking the methods open to us for "public participation" in the decision-making process, it became clear to us (1) that:

1. Guidance given to the biotech corporations is effectively advice on how to obtain "a positive opinion." The notes are full, and cover many issues, but fail to identify a clear role in the decision-making process for NGOs or independent experts.
2. EFSA is extremely reluctant to set its own research parameters or to conduct or commission independent laboratory or field studies. The most it appears to do is invite occasional outside expert opinion and set itself occasional desk study "tasks".
3. EFSA accepts substantial equivalence and safety as already established, even where hybrids are created from two or three GM lines. There is little evidence of scepticism or concern about the characteristics of multiple GM hybrids.
4. EFSA treats the protection of public health as a relatively minor matter. It is mentioned frequently, but only as a "technical issue" to be addressed in applications.

5. There appears to be no mechanism for placing the content of applications in the public domain, or for the involvement of stakeholders or independent scientists, before FSA opinions are reached and published or indeed when opinions come up for reassessment.

We came to the view that the whole approvals process was complacent, designed to "facilitate" the introduction of GM crops and foods, and to assist GM developers to extend their influence and to increase their profits. We also discovered that because EFSA opinions are formed without public participation, EFSA goes into "defensive mode" if health or safety issues later come into the frame, seeking generally to justify its original opinions. This, we felt, was profoundly dangerous. We also saw the assessment process as acting against the public interest in that the dossiers submitted by applicants could be labelled as "commercially confidential" and therefore kept away from independent scrutiny. In consequence, we presumed that only EFSA Scientific Panel members were able to view full dossiers. We wondered how this squared with EFSA's "third working principle" of maximum openness and transparency.

The handling of the MON863 application

When concerns began to be expressed about the handling of the MON863 application, we asked EFSA for information on health and safety issues. We were mindful of the doubts raised in a French study in 2004 about the contents of the Monsanto dossier (2) showing that rats fed on MON863 maize suffered serious health abnormalities. We found that in spite of these concerns, the supporting Monsanto dossier held by EFSA, and the report on a 90-day rat feeding study, were treated as secret. EFSA had long since delivered a positive -- and very premature -- assessment on the maize on 16 April 2004.

On 17 September 2004, the German competent authority submitted to the Commission and to the Member States, a commissioned re-evaluation of the rat-feeding study by Dr Arpad Pusztai. His review was not released and he was effectively "gagged" by the terms of his contract and prevented from either revealing his findings verbally or issuing copies of his report. The lack of openness, transparency and inclusiveness in this process was clearly against the public interest, and was completely unacceptable to us and many other interested parties. The behaviour of Monsanto was contemptible. When the company claimed that its full dossier including the rat feeding study was "confidential business information", it contravened EU law, which stipulates that any information concerning human health or environmental safety must be made public (3). EFSA refused to accept the evaluations of Dr Pusztai, and commissioned another brief study which turned out to be much more to its liking (4). It then (in October 2004) confirmed that its original safety assessment would stand. In the relevant committee papers, which we have seen, Dr Pusztai was mentioned by name, and openly criticized on the record, in the full knowledge that he was still gagged and would be quite unable to respond or otherwise defend himself. This was an insult both to the German authorities and to Dr Pusztai.

In March and April 2005 we formally applied for the release of Commission documents relating to MON863. After a considerable struggle, we were given access to a restricted EFSA site, and found there nothing that we did not already have in our possession. Our complaints about non-cooperation got us nowhere, and in

April we had to enter a formal complaint (for the second time) to Mr Barroso, the President of the Commission (5). In May we also entered another complaint -- this time about the treatment of Dr Pusztai.

In May 2005 there was massive media coverage when we and the French scientists at CRII-Gen leaked some of the details from the Monsanto "secret dossier" (6). We also leaked some of Dr Pusztai's conclusions which we had obtained not from the author but from sources in Europe. Monsanto came out fighting (7) and the storm of controversy intensified. We issued a press release entitled "GM Maize Conspiracy Revealed" -- an extract is copied below (8). At last Monsanto agreed that they would not object to the publication of the Pusztai evaluation, and we immediately published his main points (9). Also in May 2005 the member states, in spite of the "re-confirmed favourable opinion" from EFSA, failed to give MON863 a qualified majority. Monsanto still refused to allow access to its full dossier, until on 10th June 2005 the German authorities obtained a court ruling that Monsanto must release its full 90-day rat feeding study into the public domain. The ruling was based upon key provisions of Directive 2001/18/EC.

Finally, on 8th August 2005, the Commission used its controversial powers and gave consent for the placing on the market of MON 863 for import and processing as animal feed. That was another disgrace, in the peak holiday season, given the fact that the Monsanto dossier (which was very large) was still being digested by scientists who had only recently been allowed access to it.

Questions arising from the MON863 approval process

It goes without saying that NGOs and consumer groups (not to mention the European media) are deeply dissatisfied with the role played by EFSA in this sorry business. This dissatisfaction was expressed by FoE Europe, Greenpeace, BEE, EuroCo-op, European Public Health Alliance in its "Stakeholder Challenge" at the Stakeholder Platform in Parma (10) in October 2005. Similar concerns about secrecy and bias have been expressed in relation to many of the other "opinions" relating to GM varieties issued by EFSA since its formation in 2003. We are not concerned whether this secrecy (and the obsession with "commercial in confidence" status) is to be laid at the door of EFSA or the Commission or member government lawyers; it is profoundly bad for democracy and profoundly bad for science.

Finally, we ask EFSA for answers to the following questions:

1. Has EFSA ever seriously questioned the scientific validity of the concept of substantial equivalence, which appears to may of us to utterly worthless from a scientific point of view?

2. Has EFSA ever invoked the precautionary principle (11) as laid down in Directive 2001/18/EC, by advising against consent where "reasonable scientific doubt" about health and safety exists?

3. Why is it that EFSA appears to base its opinions largely upon the dossiers submitted by applicants for consents, when it knows (and we all know) that these dossiers are the products of "scientific advocacy" rather than independent scientific endeavour? (12)

4. How does EFSA justify its obsessive secrecy and obstructiveness in protecting data included in applicants' dossiers which clearly has nothing to do with commercial confidentiality? In other words, is EFSA capable of taking a view of its own on what is "commercial in confidence" and what is not?

5. in the case of MON863, why did EFSA persistently, over the course of more than a year, hide information from the public at the behest of Monsanto which had already been publicly accessible in the United States, Australia and New Zealand?

6. What steps did EFSA take to force Monsanto to alter its 2004-2005 stance on its "secret MON863 dossier"?

7. Has EFSA ever commissioned independent research (for example, feeding trials) into the health and safety of the GM varieties for which it has given positive opinions?

8. Has EFSA ever pressed the Commission to set up a genuinely independent laboratory at which feeding studies on GM varieties can be conducted prior to such varieties entering the approvals process?

9. What account does EFSA take of the "indirect effects" (for example associated with RR residues) of the planting, harvesting or consumption of GM varieties, as laid down in the relevant Directives?

10. How many "opinions" on GM varieties have EFSA revised or revoked in the light of new scientific evidence on those varieties or others deemed to be related in some way?

11. Does EFSA itself initiate reviews of its GM opinions, or wait for seed owners to notify the authorities of "new evidence", or for national bans which require action?

12. Has EFSA apologized to Dr Arpad Pusztai for criticizing his views on MON863 in the public domain in the full knowledge that he could not respond?

13. Has EFSA ever instructed Monsanto to make samples of its GM varieties available to independent researchers who have valid health and safety research projects under way? (The example of Prof Bela Darvas in Hungary comes to mind -- as EFSA knows, Monsanto has refused since 2003 to provide him with MON863 seed in the light of his dramatic and uncomfortable discoveries relating to MON810.)

14. Why does EFSA continue to do business with Monsanto, Syngenta and other GM corporations in view of the disdain which they persistently show towards the regulatory system? (13)

15. What is the EFSA attitude to the Cartagena Protocol, which explicitly states that "lack of scientific certainty" about potential risks of biotech products "shall not prevent" a member nation like Hungary from banning the importation of a given biotech product? (14)

16. Why has EFSA, in its opinion on the Greek ban on Topas 19/2 canola, attempted to redefine "adverse effects" so as to exclude widespread GM outcrossing, longterm irreversible changes to the ecology, and the creation of widespread feral populations

of GM oilseed rape? (15)

17. Has EFSA ever sought assurances from applicants for GM consents that they will facilitate the replication of experiments through the provision of seeds and other GM reference materials to independent researchers? And in the absence of such assurances, what credibility has EFSA placed upon their "non-replicable" research? (16)

Conclusion

We are grateful that EFSA has organized this meeting, and that it is looking to improve its methods of working and its relations with stakeholders on GM issues. We trust that our questions and suggestions will be viewed as creative rather than destructive.

But it is increasingly apparent (cf the Hungarian experience) that EFSA and the EC are expecting dramatic, comprehensive and fully worked up "new science" relating to any adverse effects of GMs in the environment or the food chain before they will vary any of their positive opinions or consents for GM varieties. This is what Dr Judy Carman calls "the burden of overwhelming proof" loaded onto those who advocate precaution. At the same time EFSA knows that government funding for new independent research is just not forthcoming, and that the seed owners will not allow their seeds or other plant materials to be utilized for potentially "uncomfortable" research. EFSA also persistently dismisses most of the evidence of harm that comes before its GMO Panel on the grounds of "insufficient rigour" or inadequate data, or marginal relevance, or lack of peer review. The situation is an affront to science and it is also ethically indefensible (16). Corruption thus becomes an integral part of the scientific enterprise.

The only way to bring sanity and probity back into the EFSA assessment of GM varieties is to act as recommended by Ignacio Chapela:

"There must be genuinely independent research into the health, safety and environmental impacts of GM crops and foods. At the very least, there must be a requirement of full disclosure by the seed owners / GM corporations in order to place GM information and materials in a public-trust domain, where they could be accessed by the public.

Requirements would include, but not be limited to:
(a) filing of specific sequences introduced into the GMO under consideration;
(b) disclosure of the number of insertions of full constructs as well as fragments thereof into the genome of the GMO under consideration;
(c) disclosure of 2-10 kbp of the genomic context adjacent to each and every insertion, both full-construct insertion and fragments;
(d) deposit of isolines and the GMO itself as seed or other suitable reproducing materials;
(e) all of this to be paid for by the industry corporately or by the company seeking to profit from a GM event or variety."

We hope and pray that EFSA will take on board these recommendations, and will use its good offices with the EC to put new measures in place which might -- not before time -- restore some trust in the GM approvals process.

NOTES

(1) EFSA "Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed". March 2005. Also information culled from the EFSA web pages, minutes and opinions.
In November 2004 Friends of the Earth published "Throwing caution to the wind, a detailed critique of the EFSA and its work on GM foods". The report can be downloaded here:
http://www.foeeurope.org/GMOs/publications/EFSAreport.pdf

(2) http://www.criigen.org/m_fs_axbis.htm
http://www.gmwatch.org/archive2.asp?arcid=3589

(3) EC legal advisers connived in this secrecy, apparently agreeing to everything asked of them by Monsanto. "Secret dossiers" of GM information accompanying approval applications would not be permitted in the United States. "The kinds of studies you discuss would be available to the public here. MON863 was indeed evaluated by our EPA. In fact the safety data submitted to the authorities (human health and environment), are routinely made available to the public, as well as any comments to the agency on the application. There appears to be no good reason why your EFSA should not also release ALL of the information on its MON863 file." (Dr Doug Gurian-Sherman, Senior Scientist, Center of Food Safety, in correspondence with Ian Panton of GM Free Cymru.)
In Australia and New Zealand, the full Monsanto rat feeding study was examined by FSANZ and it was decided that it did not merit "confidential business interest" classification. "FSANZ decided that the confidentially claim by Monsanto was not justified under the FSANZ Act" said Dr Peter Abbott (Scientific Risk Assessment and Evaluation Branch, Food Standards Australia New Zealand).

(4) "Considerations regarding the scientific assessment of the safety of food and feed from GM plants, exemplified with GM insect resistant corn (MON863) as a case," Dr Ib Knudsen for the Swedish Board of Agriculture, 13 November 2004. 7 pp (available as a PDF file)

(5) Letter to President Barroso available on request.

(6) See this:
http://news.independent.co.uk/world/science_technology/story.jsp?story=640402
"When fed to rats it affected their kidneys and blood counts. So what might it do to humans? We think you should be told. The secret research we reveal today raises the potential health risks of genetically modified foods. Here, environment editor Geoffrey Lean, who has led this paper's campaign on GM technology for the past six years, examines the new evidence."

(7) http://www.checkbiotech.org/blocks/dsp_document.cfm?doc_id=10142

(8) (extract) "..... The only information available to the public on the EFSA and other web sites is information which supports the EFSA / ACRE attitude that

MON863 is perfectly safe; all information which might be embarrassing or uncomfortable for Monsanto and the authorities has been given a "CBI" classification. In pursuit of its requests to open up the MON863 secret dossier, GM Free Cymru has written over and again to EFSA, to the President of the Commission, to individual Commissioners, and to the UK government. It has also written to the German authorities and to the EC office which deals with European "freedom of information" matters. These efforts have proved fruitless. The organization has also been asking EFSA, the Commission and the German authorities for the "Declaration of Secrecy" which prevents Dr Pusztai and others from airing their scientific opinions on the rat feeding study to be lifted, in the public interest. Again, nothing has been done. The last resort is to take the case to the European Ombudsman, and GM Free Cymru is committed to do this if a dozen or more documents which has requested are not released within the next few days."

(9) The Pusztai evaluation of the 90-day rat feeing study (September 2004) is in three parts. See this:
http://www.gmwatch.org/p1temp.asp?pid=66&page=1

(10) For information on the Stakeholder Platform (6th October 2005) see:
http://www.efsa.eu.int/stakeholder_stakeholder_consultative_platform/consultative_platform/1058_en.html
The ten demands made are supported by the European Public Health Alliance, Eurocoop, the European Environmental Bureau, Greenpeace and Friends of the Earth. The demands can be downloaded from here:
http://www.foeeurope.org/publications/2005/EFSA_stakeholders_challenge.pdf

(11) On the Precautionary Principle:
http://www.biotech-info.net/in_defense.html
Like many environmental treaties, the preamble to the Cartagena Protocol "reaffirms the precautionary approach" contained in the 1992 Rio Declaration. The protocol goes further, however, by explicitly stating that "lack of scientific certainty" about potential risks of biotech products "shall not prevent" a member nation from limiting, or even prohibiting, the importation of a given biotech product.

(12) Because the onus is on the GM applicant to provide his own "supporting science" in the application dossier and to demonstrate a lack of harm to the consumer and the environment, all of the science that comes forward will be "advocacy science" done by employees or contracted researchers, and it will be controlled and edited (ie corrupted) by the applicant. Inconvenient studies will simply not be placed in the dossier -- and the GMO Panel will never know of their existence and will thus never have a chance to assess them. Science based upon the "intent to verify" tends also to be based upon ruling hypotheses -- in this case the nonsensical hypothesis that GM varieties are substantially equivalent to their non-GM parent lines. As Karl Popper said a long time ago, science will never advance through verificaton; it must be based upon the intent to disprove and improve working hypotheses.
See "On the corruption of GM Science"
http://www.gmsciencedebate.org.uk/topics/forum/0073.htm

(13) Monsanto, for example, freely admits to having no great concerns about health and safety issues and routinely resorts to lies, intimidation, bribery and corrupt science in its day-to-day operations:

http://www.corporatewatch.org/?lid=210
http://www.gmwatch.org/p1temp.asp?pid=49&page=1
http://www.organicconsumers.org/monlink.html
..... and Syngenta is not much better:
http://www.gmfreecymru.org/news/Press_Notice8December2005.htm

(14) http://www.biodiv.org/biosafety/articles.asp?lg=0&a=bsp-11
Cartagena Protocol on Biosafety
Article 11. Procedure for Living Modified Organisms Intended for Direct Use as Food or Feed, Or For Processing. (Articles 10 and 11 state that parties to the protocol are permitted to take precautionary measures to avoid harm caused by LMOs, even when there is lack of scientific certainty regarding the extent of harm that might occur.)

(15) "Adverse effects include direct and indirect impacts on individual organisms, populations and ecosystems and should also consider impacts on social systems (e.g. changes in agricultural practices or threats to biological resources of cultural significance). A precautionary approach should pay particular attention to impacts that are widespread, long-term, not reversible, and/or accumulative."
http://www.biotech-info.net/applying.html
"The Cartegena Protocol on Biosafety: Applying the Precautionary Principle", Katherine Barrett, 2001.
But see this quite extraordinary and irresponsible statement: ""The presence of hybrids between transgenic spring oilseed rape and other Brassicaceae is not a hazard in itself and does not imply inevitable ecological damage..... The EFSA GMO Panel concludes that the likelihood for unintended environmental effects due to the establishment and spread of herbicide tolerant oilseed rape will not be different from that of traditionally bred oilseed rape."
Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Greek invoke of Article 23 of Directive 2001/18/EC1 (Question N° EFSA-Q-2004-062)
Opinion adopted on 8 July 2004 -- in blind defiance of the findings of the UK FSE research that showed that GM oilseed rape damages the environment.

(16) "Science has always operated on the assumption that experiments must be replicable in order that results may be verified or falsified. But if the GM multinationals refuse to allow their GM seeds and reference materials to be examined by anybody other than their own scientists, there is no way that anybody should trust their results, whether or not they have been through a peer review process. Integrity is immediately swept away, and corruption takes its place."
Statement from GM Free Cymru, 20th February 2006

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