PETITION TO THE EUROPEAN PARLIAMENT: EFSA AND THE FOOD SAFETY RIGHTS OF CITIZENS

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Title of Petition 0813-08: The importance of impartiality within EFSA & the food safety rights of EU citizens

My concerns arise out of the extraordinary power which EFSA's GMO Panel has accumulated, to the point where it can make decisions which might damage the health of millions of EU citizens, without any effective intervention from any other body. It is an unelected panel which undertakes risk assessments; but it carries no responsibility for risk management and it evades all legal liability for its decisions. I protest about the defective (and potentially dangerous) manner in which EFSA processes and assesses scientific evidence, and forms its "opinions" on GM products. In my submission, a bad situation of five years ago has now become worse, and not better. I also wish to state that I am very dissatisfied with the Commission responses to my Petition, which I consider to be evasive and complacent.

These are my main concerns, enumerated and elaborated (with references) in my Petition and following submissions:

SUMMARY OF MAIN POINTS

Relating to EFSA's scientific risk assessment procedures and the rights of citizens to healthy food

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1. EFSA's GMO RISK ASSESSMENTS ARE DEPENDENT UPON SELECTED ADVOCACY SCIENCE. For the most part this research is not published or peer-reviewed. Assumptions are often accepted by the GMO Panel as proven facts or hard evidence. “There is a criticism by many people that the dossiers submitted to EFSA are prepared by the companies. And so, obviously, the companies would present data that are more favourably disposed to their varieties and products. There is a huge issue with consumer confidence.... Consumers would be more confident if we had more publicly-

funded research, where the researchers had no vested interests in getting their products over the line." (Prof Patrick Wall, 4 Dec 2008) (1)

2. EFSA ROUTINELY ACCEPTS SCIENCE IN GMO APPLICATION DOSSIERS THAT IS NON-REPLICABLE. It has never, to the best of my knowledge, asked for repeat or improved experiments conducted by bodies and scientists fully independent of the applicants. Non-replicable science should NEVER be acceptable in any scientific community, since there is a possibility that it will be flawed or deliberately manipulated. And yet EFSA does not subject this selective and non-peer-reviewed science to anything like the same degree of scepticism or minute scrutiny as it applies to independent and "inconvenient" research which is brought to its attention. (2)

3. EFSA HAS NEVER CONDEMNED THE PRACTICE OF RESEARCH BLOCKING by GM patent holders and the owners of GM products. The Commission says: "Neither the European Commission nor EFSA have any influence on how companies award contracts for carrying out independent research, a situation similar to other areas of endeavour." That is completely untrue. The EC and EFSA have ample discretionary powers (a) to condemn research blocking, and (b) to prevent it from happening in the future, at least with respect to applications for approvals submitted to the GMO Panel. (3)

4. EFSA DOES NOT MAKE FULL AND EARLY RELEASE OF THE DATA CONTAINED IN APPLICATION DOSSIERS. ANY INDEPENDENT TESTING CAN ONLY BE DONE POST-RELEASE (IF AT ALL) BECAUSE OF EXCESSIVE AND PROHIBITIVE USE OF PROPRIETARY SECRECY CLAIMS. Dossier research material cannot be properly peer-reviewed by independent scientists, NGOs and consumer groups. When data is released, sections that have no need for commercial confidentiality are blacked out or withheld, and obsessive secrecy / access conventions are enforced. This is not in line with EFSA's duties of openness and transparency. Researchers outside Europe cannot access the material at all. (4)

5. EFSA's GMO PANEL HAS A STRONG PRO-GM BIAS. It is also non-elected, and carries no legal liability for its decisions, opinions and advice. "EFSA’s GMO panel is populated by experts who are comfortable with the technology; you have a lot of molecular scientists who have been playing around with recombinant DNA technology since 1969... and many of them use it in their laboratories and their research institutions and they’re quite comfortable with it; and so — for them — they wouldn’t see the same risks that maybe a citizen would see." (Prof Patrick Wall, 4 Dec 2008) Where ad hoc "experts" are invited by the GMO panel to assist in the formulation of

opinions, they are always carefully chosen so as to facilitate the approvals process and to confirm EFSA's own risk assessments. (5)

6. EFSA DOES NOT EFFECTIVELY ENGAGE WITH STAKEHOLDERS. From personal experience, the consultation process is designed to discourage comments. In post-consultation summaries, it impossible to see who has made which comments, and which comments have been acted upon. It appears to me that all comments considered to be "inconvenient" are simply dismissed out of hand, in spite of EFSA assurances to the contrary. (6)

7. EFSA TAKES NO ACCOUNT OF SOCIO-ECONOMIC FACTORS. In 2008 the representatives of the 27 EU member states unanimously criticized the present GMO approval system and called upon the Commission to ensure a more rigorous and impartial risk assessment and to take into account the social and economic impacts of GMO cultivation in Europe. The Commission should have done this long ago, under the terms of Directive 2001/18/EC. I am aware that Member States must "collect and exchange" information on socio-economic risks and benefits by July 2010. But in the meantime, in the EC's recent approvals for GM products, there is NO RECOGNITION of the validity of socio-economic factors. (7)

8. EFSA DOES NOT ENCOURAGE TRULY INDEPENDENT STUDIES OF GM SAFETY. The Commission says that "applicants are obliged to provide studies, including independent peer-reviewed studies, to demonstrate that the GMOs do not have adverse effects on human or animal health or the environment." That is not true. According to the agreed text from the Environment Council (4 December 2008): "Member States and the Commission should ensure that systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted; NOTES that the necessary resources should be secured for such research by the Community and Member States in accordance with their budgetary procedures, and that independent researchers should be given access to all relevant material, while respecting intellectual property rights; INVITES the Member States and the Commission to collect and exchange information on this research." In fact, there is a lower emphasis on independent research today than there was in 2008. (8)

9. EFSA GUIDELINES COMING INTO LAW WILL LOWER SAFETY AND REGULATORY REQUIREMENTS. The Commission says that in finalising the new GMO Implementing Regulation it will "further specify the requirements for applications submitted...." This implies that the

requirements will be tightened up. Unfortunately, the reverse is true. A close examination, clause by clause, indicates to me that EFSA will get derogated powers to decide that in many cases hardly any new research will be needed prior to "positive opinions" being issued. In any case, EFSA's risk assessment procedures fall far short of the guidelines adopted unanimously by the EU and all member states in the UN's Codex Alimentarius. (9) The full results of the current consultation process must be available -- and acted upon -- before a modified Draft Implementing Regulation is brought into law.

10. MEMBER STATES INVOLVEMENT IN GM APPROVALS IS REDUCED. The Environment Council Conclusions of 4th December 2008 called for greater involvement by Member States in the assessment of applications and the formulation of opinions on GM products. It also called for EFSA to exercise vigilance in order to identify at an early stage any potential divergence between scientific opinions, and to cooperate with Member States and national bodies with a view to resolve or clarify the contentious scientific issues. However, there is now LESS involvement from member states -- for example, the UK regulatory bodies do not even look at application dossiers any longer, claiming that EFSA is the body legally constituted to do this work, and claiming that it wishes to avoid duplication of effort. (10)

11. EFSA KNOWS THAT IN GIVING GMO APPROVALS, THE COMMISSION ACCEPTS ONLY EFSA ADVICE. The Commission takes no account of divergent (and precautionary) opinions expressed by Member States or by independent scientists or by consumer groups or NGOs. In my submission, that is dangerous, and the Commission is of course entitled to accept or reject EFSA advice, depending on individual circumstances and the application of the Precautionary Principle. In effect, the Commission and EFSA, working together, have the power to ignore or overturn the expressed wishes of the European Parliament. (11)

12. EFSA AND THE COMMISSION APPEAR UNWILLING TO ACCEPT THAT THERE IS UNCERTAINTY IN GM SCIENCE, AS IN ALL SCIENCE. Since EFSA only appears to look for evidence of acute toxicity in its safety assessments, it routinely dismisses the abundant signs of immediate, long-term or chronic toxic effects described in the peer-reviewed literature. Some of these effects are described as "pre-cancerous conditions." In ignoring or dismissing such effects, EFSA fails to apply the Precautionary Principle and turns its back on its duty of care towards European consumers. (12)

13. EFSA IS ABLE TO CONTROL THE GM RESEARCH AGENDA AND TO RESTRICT ACCESS TO INFORMATION AND RESEARCH MATERIAL IN

ITS POSSESSION. Information is power. EFSA has resisted independent peer-review of dossier material and seems to be intolerant of contrary opinions. This may be interpreted as a sign of an insecure and beleaguered organization! BUT EFSA must accept that the current access restrictions which it imposes (as in the case of LL601), through the excessive and also illegal application of IPR rules, is a cross-cutting problem for all concerned scientists and citizens. The problem MUST be addressed. (13)

14. EFSA HAS NEVER, TO THE BEST OF MY KNOWLEDGE, EVER ADMITTED ANYWHERE THAT THERE IS SUCH A THING AS INSERTIONAL MUTAGENESIS OR TRANSFORMATION-INDUCED MUTATION. This denial is maintained in spite of abundant evidence of this mutagenesis (which can affect the safety of GM crops and foods) in GM crop-breeding programmes. The EFSA position (as with the position on synergistic and indirect effects) is related to the dogma that GM crops are "substantially equivalent" to their parent or non-GM lines. (14)

15. CONSUMERS DO NOT WANT GM FOOD. "GM food has no benefits for consumers... EFSA is a consumer protection agency; it is not meant to rubberstamp biotech dossiers..... We cannot force-feed European citizens products that they don't want. We live in a democracy. People have a right to have objections..... If people don't want (GM) technology they have a right not to have it." (Prof Patrick Wall, former Chairman of EFSA, 4 December 2008). EFSA's GMO Panel sees its prime purpose as the facilitation of consents, and the EC sees its prime purpose as "opening the market" to GM products -- and they both argue that the consumer must have choice, to eat or not to eat GM food. But there is NO DEMAND for GM food -- does anybody know anybody who has actually asked for it? (15) EFSA works to a very narrow brief, related to risk assessment -- but it does have a duty of care towards the citizens of Europe, whose opinions and aspirations must be given high value.

SUMMARY

As many NGOs, consumer groups, and politicians have become aware, there is no longer any democratic involvement in the risk assessment and approvals process for GM products for food and feed use, and for commercialization in the EU. EFSA and the Commission hold all of the power, and there are no effective checks and balances to ensure that this power is not abused. EFSA makes its own guidance rules and application

and assessment procedures, and decides how it will interpret them. In some cases EFSA is the only body that scrutinizes dossiers, and it resists attempts from others who wish to have an input into the process. It works with the Commission over and again to "facilitate approvals", to subvert the will of the Parliament, and to go against the wishes of the people of Europe, who see NO benefits accruing to them from the use of GM crops and foods. Increasingly, EFSA is involved in the watering down of the regulatory process, and it is moving into the policy field as well. EFSA is driven by the desire to see more GM crops and foods in the market-place, and the Commission is driven by the desire to appease the biotechnology multinationals, the WTO and the USA and its GM-producing partners.

I respectfully ask the Petitions Committee, and the Parliament, to curb the power of EFSA in the interests of the people of Europe. I consider that my health, and the health of millions of other consumers, are threatened because EFSA is in a state of denial about the physiological effects being shown up, over and again, in animal feeding experiments. Thousand of others see these effects, and are alarmed by them, but EFSA and the Commission simply brush them aside as being "biologically insignificant." This is exactly what happened when the lethal effects of asbestos and certain pesticides were first described in scientific studies.

REQUESTS FOR ACTION

In spite of these 15 serious problems, I consider, like many of my colleagues in NGOs and consumer groups, that it is not too late for the Parliament to take action to increase its own authority in the matter of GM policy and to enhance the protection of EU citizens. The Commission and EFSA appear to have done remarkably little to implement the recommendations of the Environment Council of 4th December 2008. I therefore respectfully ask the Committee to bring forward the following suggestions to the Parliament:

1. Place it on the record that the Parliament will insist that EFSA's GMO Panel must be reformed to include at least 4 representatives from NGOs and consumer groups, as a means of increasing public confidence in its operations.

2. Place it on record that all research contained in application dossiers MUST be replicable, and that applicants will henceforth be required to confirm in writing, in advance, that they will provide their genuine GM products,

comparator isolines and reference materials to independent researchers who request them for bona fide safety studies -- if necessary, prior to approval being given.

3. Parliament should condemn, by resolution, the following:
   (a) over-dependence upon scientific evidence produced entirely under the control of the applicant;
   (b) the use of any results from scientific experiments that are, for whatever reason, non-replicable;
   (c) the blocking of independent research through "non-cooperation" by GM corporations and patent holders.
   (d) any actions by EFSA to prevent open and early release of full research dossiers for peer review BEFORE the formulation of opinions and the issue of consent;
   (e) any attempts by EFSA to water down or speed up application / assessment procedures for future GM products;
   (f) any attempts to "simplify" the safety study requirements for "stacked" GM events;
   (g) the vilification and intimidation of independent scientists who happen to discover GM-related health and safety effects which are "inconvenient" to EFSA and to the GM patent holders.

4. Parliament should insist that truly independent studies relating to the safety of GM products are ALWAYS brought into the risk assessment process and given due respect.

5. Parliament should encourage greater involvement by the Member States in the GM risk assessment process, and should remind both EFSA and the Commission that where there is disagreement and uncertainty, the Precautionary Principle should always come into play, with a view to providing maximum protection for the health of European citizens.

I am very grateful to the Committee for allowing me to bring this Petition forward, and I respectfully ask for careful consideration of the points I have raised.

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