Submission to the Scottish Parliament Health and Community Care Committee Inquiry on GM crops, 2002

The Munlochy GM Vigil Petition signed by over 6,500 people requests a halt to GM crop trials and a debate on the future of GM in Scotland. This is supported by a document of submissions initially presented to the Public Petitions Committee. We request you refer to this document which expresses the strong public and scientific concerns surrounding the health effects of GM crops especially the submissions from HIGMC, Highland Council, The Soil Association, Malcolm Hooper, Susan Bardocz, Jeremy Bartlett, Arpad Pusztai, ISIS "Hazards of GM Crops" and "Horizontal Gene Transfer."

There are two kinds of uncertainty. The first is risk, which is an event with a known probability. Second, there is true uncertainty, which is an event with an unknown probability. This is where there has been insufficient experience of the product or process to provide the information about the probability of harm, for example, the products of GM technology. To deal with "risk" uncertainty policy makers have developed a process called "risk assessment" which is useful when the possibility of an outcome is known from experience. However, if conventional risk assessment is applied to problems characterised by true uncertainty it can quickly turn into guess-work. The precautionary principle or approach has been developed to deal with such situations. "In the case of GM foods and crops an unknown level of risk is posited to an unknown number of people as the mechanisms involved are still so little understood" (NCC report Public Health and the Precautionary Principle, October 2000).

The framework for approval of GM crops and food is based on substantial equivalence. This has never been properly defined, and there are no legally binding rules on how to establish it. It has been described "as a pseudo scientific concept because it is a commercial and political judgement masquerading as if it were scientific. It is moreover inherently anti-scientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests. It therefore serves to discourage and inhibit potentially informative scientific research". (Millstone, Brunner and Mayer, October 1999)

Substantial equivalence asserts that plants whose fundamental genetic structure has been permanently altered are no different from naturally occurring varieties. In making this claim manufacturers only have to perform cursory tests for nutrition, flavour and texture. Other concerns on this concept have been highlighted by amongst others the Medical Research Council stating it "involves a somewhat subjective judgement" and the Royal Society of Canada calling it " scientifically unjustifiable"; even the Royal Society (UK) seems now to desire a more rigorous approach. A more rigorous approach would be for legislators to treat GM products in the same way as novel chemical compounds such as pharmaceuticals, pesticides and food additives and to require companies to conduct a range of toxicological tests. The lack of such rigorous assessment has led to a plethora of concerns surrounding GMOs being released into the open environment. Some of these well-founded concerns on the effects of this on human health are quoted below:

"Some of the world's most distinguished scientists say that it is possible that swapping genes between different species could create new diseases for which there is no cure…… the probability may be small but the consequences may be catastrophic" John Humphrys (Sunday Times 1st July 2001)

Forty Irish GPs demanded a ban on GM Foods using the word "unbelievable that Irish Government report said GM food was safe. The report stated: "The scientific evidence about the safety of current GM food products is supported by the absence of reports of adverse effects from their consumption." Doctor Elizabeth Cullen co-chair of the Irish Doctors Environmental Association said that "there had been a recent increase of allergies to soya among Irish children and there was no way to tell if it was related to foods containing GM soya products because of lack of labelling."

US concern was expressed in The New York Times, (5/4/01) by Martha Herbert (paediatric neurologist at Massachusetts General Hospital, Boston): "Although scientists are well aware that genetic engineering can produce unexpected often highly undesirable effects, there is no current testing or health monitoring to detect these health and environmental curve balls."

Professor Terje Traavik Head of Dept of Virology, Tromso, Norway said, "The existing generation of GMOs came from crude and potentially unsafe scientific methods". The Norwegian Biotech Advisory Board have stated that because of the difficulty of controlling just where the injected gene locates itself in the DNA chain it is not possible to predict all unwanted effects.

Dr Michael Fox (Humane Society US) "New diseases may also evolve as a result of transgenic viral recombination with other viruses and because of alterations in the transgenic organisms physiology, especially immune system function and response to stress and infection."

Arpad Pusztai is quoted as saying "They push something, which is not properly tested and is potentially dangerous on to us and give us no choice … adequate studies have not been done. Because the companies when they release these things never tested them properly, it is our job to see what potential hazards we can have. With irreversible GM technology this becomes even more important as you have no chance of having a remedy." Some of Pusztai's research has caused scientific controversy; however it is noticeable that no other scientist has repeated or continued the research.

Dr Barry Commoner (City University, New York) "What the public fears is not the experimental science but the fundamentally irrational decision to let it out of the laboratory into the real world before we really understand it…..genetically engineered crops represent a huge uncontrolled experiment whose outcome is inherently unpredictable. The results could be catastrophic."

Harash Narang (Microbiologist and Senior researcher, Leeds University: one of the first to claim a link between BSE and vCJD) stated "If you look at the simple principle of genetic modification it spells ecological disaster. There are no ways of quantifying the risks. The solution is simply to ban the use of genetic modification in food".

Sunday Herald (June 2002) stated that a senior MAFF official (1999) stated "there is cause to be concerned about the problem of gene transfer to environmental organisms. Such bacteria could also act as a gene pool that may interact with human pathogens. Transfer of genes may pose a much more significant threat to the very young, the elderly and those who are immuno compromised".

The French Food Standards Agency has called for more testing into the long-term effects of GM on immune systems, allergenicity and reproduction.

There are also specific concerns surrounding GM pollen as GM techniques allow for the incorporation of new sequences from very diverse sources including proteins not found in conventional foods which may lead to exposure to a new range of potentially allergenic proteins, and yet, Professor Jean Emberlin (National Pollen Research Unit, University College, Worcester) could find no specific publications on the potential alterations in allergenicity of pollen from GM crops. (Committee on the Medical Effects of Air Pollutants, February 2002)

The Consent application process for the GM OSR grown in Scotland, MS8 RF3, was initiated through Belgium. Eight EU countries rejected the application and it was noted that there was insufficient data on pollen. Only the UK and Germany were in full support of the application. Belgium in fact refused consent for GM OSR trials in 2002 because "despite strict measures put in place it was impossible to prevent leakage of modified genetic material from OSR to the environment".

In the face of all this concern one would expect the applications themselves to contain results from tests proving that all elements of the crops present no risk to human health. However, throughout the 5-year period which Aventis refer to as proof that their product was safe, the only tests carried out were on the tolerance to and efficacy of glufosinate ammonium. Their basis of no risk to human health comes entirely from the fact that "no risks" were observed during this period. Further, in their initial submission to the Health Committee they explain this process by noting that "many of their employees and contractors have been in contact with transgenic plants during greenhouse and or field activities but that no indication of changed allergic reactions had been identified". SCIMAC (the GM industry body) in their initial submission to the Health Committee, stated "the only adverse effect on human health associated with GM crop trials currently taking place is likely to be suffered by the GM trial growers themselves as a result of the stress they have experienced due to mindless protests of anti-GM campaigners".

Many requests have been made by various bodies, and individuals to access health tests carried out by the GM companies and at present no research has been forth-coming. In fact, it is widely believed that no peer-reviewed publications of clinical studies on the human health effects of GM exist.

Safety assessments seem to be based on theory and small-scale empirical observation. When there are fundamental widespread concerns and risks, surely there is a necessity for rigorous independent peer-reviewed scientific testing.

"No evidence of harm" is not equivalent to "there is evidence of no harm."

The risk assessment procedure is once again predicated on substantial equivalence. It is based around expected events, and this is its major failing. It pays no recognition to unknown and unanticipated effects.

The public however does recognise the limits of scientific "knowledge" and the often exaggerated claims made by scientists and the policy bodies that they advise. Regulatory frameworks are often seen as compromised by prior political commitments, conveniently ignoring inevitable ignorance and lack of capacity to imagine future eventualities that may arise. Traditional risk communication typically sees the process as an "add-on" at the end of the risk management process, exemplified as "we make the decision then we tell you what the decision is". At best this can be seen as information provision, at worst, it could be described as miss-information provision. (NCC: Risk and Regulation, June 2002) The "testing" is done by the companies themselves, and then assessed by ACRE. In spite of numerous requests, the public still have no idea what scientific material has been assessed by ACRE and whether material presented by scientists sceptical about the safety of GM crops has been adequately considered.

When the application for MS8 RF3 came before this ACRE committee eight of the thirteen members had proven links to the biotechnology industry whilst another had worked on a MAFF contract to assess methods for influencing public opinion on biotechnology. These members were eventually removed. However the crop and crop trials had been assessed as safe.

Sherwin Shih (Dept Social Science, University of Middlesex) reported that "Nowhere in the public documentation is there any evidence that ACRE has questioned the quality of risk assessments provided or the value of monitoring reports or required consent holders to provide updated information about the risk of releases. In these circumstances, ACRE has showed a poor standard of scrutiny and has thus undermined the Regulations that have been established as protection from the impacts of GMOs."

It should be noted here that ACRE (31st July 2001) stated "It is not the committee that gives consent for the release of GMOs. It is ACRE's role to advise ministers on the potential risks and ministers decide whether or not to issue the Consent. Ministers are not obliged to take ACRE's advice".

In spite of claims that the risk assessment and regulatory regimes are robust, there have been numerous regulatory failures across the UK and world-wide, including:

ACRE ignoring an animal feed study where double the expected number of chickens died from eating transgenic (T25) as opposed to conventional maize. Aventis's inability to "put the right seeds in the right bag" needlessly leading to releases of antibiotic resistant marker genes into the environment. Starlink corn unapproved for human use entering the food chain and causing allergic reactions. The regeneration in the UK of GM crop trials in the following year needlessly releasing more GM pollen into the environment.

The attitude of the biotech companies themselves to risk assessment can be summed up by the following: "Monsanto should not have to vouchsafe the safety of biotech food. Our interest is in selling as much of it as possible" Phil Angell (New York Times)

It is small wonder then that there is no liability for damage incurred and insurance companies such as NFU Mutual refuse to give any cover for GM crop trials. Swiss Re (Zurich based) has declared that "risks from GM food and crops are incalculable."

We must also look at trajectories at this point, commercialisation is possible, GM animals are presently being developed and pharming is also currently being considered. Risk assessment procedures and associated regulations need to be reformed now, as their inability to cope with the present situation gives absolutely no confidence when we look to the horizon.

Inadequate separation distances have led to GM DNA inadvertently getting into the food chain via control crops and contaminated honey. The Czech Republic demands separation distances of 200m, we have already noted Belgium's position, and the Advanta seed incident where thousands of acres of the UK was illegally planted with GM OSR was caused by cross-pollination in Canada, where the regulations stipulate 800m separation distances (it is worth noting that even at this distance 23% of the seeds had greater than 1% GM contamination and still the Executive refused to test GM OSR 50m from the GM trials prior to it being sold).

SCRI research (Research report No.12 - Feral Oilseed Rape Populations) infers that cross-pollination is "inevitable".

The importance of the adequacy of separation distances is inferred by ACRE (31st July 2001), when it states "No OSR grown within 50m of a release is permitted to enter the food chain and must be treated as GM".

The latest honey contamination incident in Newport occurred over 2 miles from the GM trial site and led Tim Lang (Professor of Food Policy at Thames Valley University) to declare "The early assurances from the industry and government that a buffer zone would allow safety and choice for consumers are falling apart. It raises environmental and health worries and what we don't yet know is whether these warnings will translate into a risk to human health". Twenty-four beehives were placed right beside the GM OSR trial at Munlochy.

The response from the FSA to the Newport honey contamination incident concluded that "it was improbable that there is any risk to consumers from the presence in honey from GM plants". Their conclusions were drawn from a workshop the ACNFP held on 15th October 1991 due to the lack of data on pollen from GM plants being available. It stated that allergies to specific types of honey from non-GM plants had been recorded but no studies had been carried out to discover whether there was any link between allergy and the consumption of pollen. The workshop suggested that toxin proteins produced by genes inserted to increase pest or disease resistance could cause problems to consumers if found in the pollen from GM plants. It then concluded that: "although it could not disregard the

possibility that the presence of pollen from GM plants in honey might raise problems of consumer health and safety, there was at present no need to limit releases of GM plants as the current procedure involving case-by-case evaluation of all releases of GM organisms by ACRE provided adequate safeguards"

There is uncertainty about the effects GM crops have on human health. This can clearly be seen in the statements made above and the often quoted position and doubts expressed by the BMA. The UK Rural Affairs Secretary, Margaret Beckett has also said "there would have to be a further independent review to satisfy the government that GM technology had no adverse effects on human health". (Times 19th January 2002) Michael Meacher UK Minister for the Environment responding to the AEBC on the limitations of the FSEs (22nd February 2001) stated "there may well be continued uncertainty concerning any possible direct and indirect effects on human health arising from the genetic modification of crops".

"Long-term monitoring of the effects of GM is important because allergies to the new modified proteins could take years to show up" (Ham Pong, Ottawa allergist)

If GM crops are to be tested, testing their effects on human health must surely be paramount.

History is littered with examples where early warnings of future effects were ignored and society faces the effect today. Forestalling disasters requires acting before there is strong proof of harm, particularly if the harm may be delayed and irreversible. This is an approach to scientific evidence and policy making called the precautionary principle. Warnings were given over asbestos, DDT, Thalidomide, PCBs and BSE sometimes up to a century before any action was taken. We are presently in a position where we either repeat history or honestly accept that the present basis and regulations that allow GMOs to be grown in the open environment is woefully inadequate and potentially catastrophic. The time to reassess the present situation is now whilst GM crops are at an experimental stage. There is no short-term economic pressure and no public demand. If the situation is not retrieved in the very near future it will become increasingly more and more difficult to ever do so. An opportunity has been presented to the Committee to put public health above all other interests.

It is worth noting at this stage the problems that led to the fatal and costly BSE disaster: "Expert advisers were carefully selected and those who did not share the Ministry's policy framework or who might refuse to acquiesce to restrictions on the dissemination of information were excluded".

"The UK Public Health Laboratory Service - the established disease surveillance institution in the UK for new and emerging diseases - was always excluded from BSE policy".

"Many key experiments were never started or were seriously delayed, information and evidence were sometimes withheld and data and materials were not always shared with other researchers".

"Too little was invested in scientific research and the involvement of independent scientists was actively discouraged".

"Safety assertions that were made were not only misleading but also made it increasingly difficult for Ministers to take a range of precautionary steps".

(The above have been quoted from Chapter 15 of "The Precautionary Principle in the 20th Century" published by Earthscan.)

The key findings of Phillips report (post BSE) included:

Failure to undertake systematic or complete risk assessment or regular reassessment of risks or commission relevant research.

Lack of transparency and openness, including concealment of political framing objectives of "scientific" risk assessment and failure to make uncertainties and gaps in knowledge explicit.

Risk management responsibilities of Ministers and officials were displaced onto scientific advisers

The effects on health from GM crops will be irreversible. GM DNA will remain in the environment (in its widest terms) long after their use is discontinued. This dramatically increases the risk associated with a false diagnosis of potential hazards, and with other detrimental effects of which science is still unaware. Surely the release of irreversible and persistent elements into the environment demands a response be implemented on the sole basis of precaution, which should include systematic, comprehensive and thorough investigations of perceivable negative effects. Should new information become available associating any new negative effects to irreversible, persistent elements such as GM DNA, the financial and technological resources required for remediation are likely to be out of reach. The present situation for GM crops demands a moratorium to enable more research to be carried out, in this case its effects on human health. This research must be rigorous, independent and peer-reviewed and without it there will never be any trust that GM food crops are safe in terms of their effects on human health.

The Munlochy GM Vigil