MEDIA RELEASE GM-FREE IRELAND, 3 MARCH 2010

EUROPEAN COMMISSION EXCEEDING ITS POWERS TO APPROVE MORE GM CROPS

• Scientists denounce sinister move to weaken risk assessments

GENEVA — European MEPs, scientists, and NGOs have accused the European Commission of exceeding its powers in a sinister move to fast-track the approval of more GM crops for cultivation in the EU [1].

European scientists with long-standing expertise in GM issues took action after discovering by chance that the Commission has notified the World Trade Organisation of a new European Draft Regulation [2] to drastically weaken the implementing rules for GMO applications and assessments. [3]

The 66-page Draft Regulation was put together by the Commission and the European Food Safety Authority (EFSA) with backing from an "expert panel" including national representatives from the EU member states — without participation or the Environment Council or the European Parliament, and apparently without any scrutiny or input from the national "competent authorities" [4] which are responsible for receiving GM applications and implementing GM policy on the ground (and which are also legally and economically liable for contamination caused by GM seeds and crops) [5].

The EC notified this draft regulation directly to the WTO for a period of consultation lasting from 12 January 2010 to 13 March 2010, and declared its intention to adopt it in May 2010 and bring it into force in June 2010. There was no "notification" anywhere in Europe, no publication on any relevant EU website, and no consultation process for comments to be received and considered. EFSA controlled the drafting process and then "sold" it to the "expert panel" national representatives on the pretence that the new rules would increase consumer safety and ensure stricter control of GMOs. Their impact, if adopted, would be quite the opposite.

On 22 February 2010, the scientists sent a formal letter of complaint [6] to the President of the European Parliament Jerzy Buzek. The scientists sent similar letters [7] to the President of the European Council Herman Van Rompoy, to the President of the European Commission Jose Manuel Barroso, and to the European Commissioner for Health and Consumer Policy John Dalli.

The scientific experts describe the Commission's back-door move as a "sinister trend" and request that the EC hold back the Draft Regulations, subject them to careful scrutiny, and amend them to protect the safety and health of the people of Europe. In a related press release [8] the scientists said they only became aware of the Draft Regulation by chance, and describe the Commission's secretive move as an "illegal policy change":

"We think this is the most secretive, opportunistic and cynical attempt which the Commission has ever made to force GM crops into our fields and to thrust GM foods down our throats, even though the people of Europe have said over and again that they have no taste for them... It is clear to us that the Commission has far exceeded its powers by seeking to introduce —quite illegally — a raft of new GM policies when its powers are in fact limited in the GMO field to the introduction of implementation rules. On this basis, European scientists have made a formal protest to the Parliament and the Council of Ministers on the grounds that the Commission has broken the law. They demand that these Draft Regulations be stopped in their tracks and —in view of their great importance— be brought under proper scrutiny by the Parliament with a period of open and democratic consultation." [9]

The GM-free Ireland Network has written to all the Irish MEPs (apart from Mairéad McGuinness [10]) requesting the European Parliament to take urgent action to stop the Commission from implementing this undemocratic move before the Commission President José Manuel Barroso signs the new regulations into law. GM-free Ireland co-ordinator Michael O'Callaghan said "Cultivation of any GM crops on the island of Ireland (such as the antibiotic-resistant industrial-starch-producing GM potato approved yesterday by the Commission [11]) would destroy Ireland's untapped economic potential to secure the safest, most credible GM-free food brand in the EU" [12]. We can't allow the Commission to take this from us."

ENDS

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NOTES FOR EDITORS

1. Commission slammed for illegal GM policy changes.
   Press notice from GM free Cymru (Wales), 23 February 2010:
   http://www.gmfreecymru.org/news/Press_Notice23Feb2010.htm

   Scientists from across Europe have today made a formal complaint to the EU Council of Ministers and the European Parliament on the grounds that the Commission has illegally and unilaterally introduced policy changes in the field of GM crops and food.

   By law, the Commission is allowed to bring in "implementing regulations" and rules which will assist applicants and regulators in the interpretation of EU policy and in preparing and processing applications for GM consents (1). Specifically, Directive 2001/18 and Regulation 1829/2003 allow for "implementing regulations" to follow, and a number of these have already been brought in and acted upon. However, the Commission, as the EU's executive arm, has no right to make policy; like all executives, it is supposed to advise and inform, and bring forward measures for consideration by the democratically elected body (the European Parliament) which will approve them or not, as the case may be.

   For some years there has been increasing tension in the matter of GM crops and foods, with the people of Europe expressing their ongoing distaste for them, with the Environment Council (2) expressing extreme dissatisfaction about the operation of EFSA (the body charged with assessing the safety of GM crops and foods, and processing GM applications), and with the Commission repeatedly giving consents for GM varieties to be commercialised or used in food and animal feed against the wishes of the majority of European governments. The Commission is also under intense pressure from the biotechnology multinationals (including Monsanto and Syngenta) and from the US government and the WTO to speed up the regulatory process and to open the door to a widespread adoption of GM technology in the European farming industry.

   Against this background the Commission has been seeking for some years to "water down" the regulatory process and to appease the WTO and the USA, following the high-profile trade dispute on GM issues which took place some years ago. This has caused fury in many national governments, and among NGOs and consumer groups, who have never been convinced that GM crops and foods are (a) safe, and (b) actually wanted by anybody.

   About a week ago a group of scientists noticed that a new Draft "Commission Regulation" had appeared not on any relevant European web- site, but on the WTO web site (3). Formally, it was "notified" to the WTO for a period of consultation lasting from 12th January 2010 to 13th March 2010, with the declared intention that it would be adopted in May 2010 and brought into force in June 2010. The document, 66 pages long, had been put together by the Commission and EFSA, with the help of an "expert panel" including representatives from the EU member states. There has been no involvement by the Environment Council or the European Parliament, and the Draft Regulation has not been shown to the "competent authorities" who are responsible for receiving GM applications and implementing GM policy on the ground. There has been no "notification" of this Draft Regulation anywhere in Europe, and no process for comments to be received and considered. The drafting process was controlled by EFSA, and "sold" to national representatives on the drafting "expert panel" on the grounds that the new rules would increase consumer safety and ensure stricter control of GMOs. In fact, the Draft regulations, if adopted, will do precisely the opposite.

   Commenting on this situation, Dr Brian John said: "We think this is the most secretive, opportunistic and cynical attempt which the Commission has ever made to force GM crops into our fields and to

thrust GM foods down our throats, even though the people of Europe have said over and again that they have no taste for them. We have now looked at the Draft Regulation, and it is clear to us that the Commission has far exceeded its powers by seeking to introduce -- quite illegally -- a raft of new GM policies (3) when its powers are in fact limited in the GMO field to the introduction of implementation rules. On this basis, we have made a formal protest to the Parliament and the Council of Ministers on the grounds that the Commission has broken the law. We have demanded that these Draft Regulations be stopped in their tracks and -- in view of their great importance -- brought under proper scrutiny by the Parliament with a period of open and democratic consultation."

Ends

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NOTES

(1) The Commission issues Regulations relating to "detailed rules for implementation." The Parliament and Council together issue Regulations on matters of policy, risk, authorisation procedures and so forth. For example: Regulation (EC) No 641/2004 of the Commission of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation [Official Journal L 102, 7.4.2004]. The new Draft Regulation should be listed here, but is not: http://europa.eu/legislation_summaries/agriculture/food/l21154_en.htm - AMENDINGACT

(2) EU MINISTERS AGREE TO MUCH TIGHTER GM CONTROLS ** More devolution of decision-making ** Curtailment of EFSA powers http://www.gmfreecymru.org/news/Press_Notice05Dec2008.htm

http://register.consilium.europa.eu/pdf/en/08/st16/st16882.en08.pdf

http://www.ieep.eu/publications/pdfs/eu.../poll_health_26_jan_09_epgmo.pdf

(3) Draft Commission Regulation on implementing rules concerning applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Regulations No (EC) 641/2004 and (EC) No 1981/2006 (66 pages, in English). E-mail: ec-tbt@ec.europa.eu

2. Draft Commission Regulation on implementing rules concerning applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Regulations No (EC) 641/2004 and (EC) No 1981/2006 (66 pages, in English).

   The text is available on the EU-TBT (Technical Barriers to Trade) website : http://ec.europa.eu/enterprise/tbt/

   It can also be downloaded at http://members.wto.org/crnattachments/2010/tbt/eec/10_0030_00_e.pdf

   It is interesting —and disturbing— that the pdf of the whole Draft Regulation is only available via the Europa/Enterprise/Technical Barriers to Trade website, and is NOT available on EU sites relating to health, environment, food safety etc. (as of 22 February 2010).

3. The group of scientists with expertise in GM issues (see note 6 below for names) summarised the significant scientific and safety concerns in the Draft Regulation as follows:

   (i) REDUCED VIGILANCE. There is a noticeable lessening of vigilance on GM safety issues. With respect to feeding studies, we see an increasing emphasis on the nutritional equivalence of GM

food/feed and a pretence that this can give guidance on health and safety. We know already that the majority of feeding studies submitted in application dossiers are not safety studies at all, but are concerned primarily with nutrition and productivity. In several places the Draft Reg text suggests that for nearly all GM food and feed varieties, "sufficient experience is available" for assumptions to be made about safety and to suggest that further studies are unnecessary. We dispute that contention. Elsewhere there is the comment that experimental testing "may be necessary" involving laboratory animals. That allows applicants to avoid lab tests if they can claim that a new variety coming forward is "substantially equivalent" to something already tested in the past. That is complacent, and it is bad science.

(ii) DEROGATIONS AND DEALS. By watering down the regulatory requirements for animal testing, toxicology studies etc, there is a distinct possibility that EFSA can in future make convenient "deals" with applicants to bypass almost all of the studies that should be done. For example: "By way of derogation from paragraph 1, an application may be accepted even if it does not satisfy all the requirements set out in that paragraph, provided that the applicant submits verifiable justification for each element not complying with those requirements." Again: "........when studies have been already submitted for the purposes of an application to the European Food Safety Authority, a reference to such studies and the results of the evaluation may, with the agreement of the Authority, be made in the framework of another application...." Under "Toxicology" there is a paragraph which allows the applicant to "state reasons" why he does not need to submit required or recommended studies in order for a sound ruling to be made on safety and risk. We can take it as read that EFSA will be very accommodating.....

(iii) STACKED EVENTS. We have particular concerns about the method proposed for dealing with "stacked event" applications. "Second generation" GM crops, including those with supposedly enhanced nutritional value, are likely to be non-uniform and unstable because they have complex introduced traits. If two or more GM lines are hybridized to introduce "stacked" GM traits, the potential dangers become even greater because of synergistic effects. And yet it seems to us from a reading of the Draft Reg that applications for these complex varieties can be pushed through along a "fast track" process with simplified requirements, as indicated above. Applicants can simply provide a "scientific rationale justifying that there is no need for experimental data" for the relevant "sub-combinations." On the contrary, "stacked event" varieties should NEVER be approved for cultivation or use unless thy have been through a MORE onerous safety testing regime than the "single trait" varieties from which they are bred. There is a further, quite deliberate, muddying of the water. If it can be claimed that the stacking was done by conventional breeding (even if the lines used are GM lines) all that is needed is an "assessment" of nutritional or compositional changes, and "no further studies shall be recommended." (1.6)

(iv) RESEARCH STANDARDS AND PROTOCOLS. There is a distinct lack of clarity about the precise safety testing regime that should be employed with respect to new GM varieties. For example, applicants are simply urged to take into account relevant international standards, such as the guidelines of the Codex Alimentarius and the OECD for the conduct of food safety assessments on GM plants. Again, the text indicates that studies presented in applications "should" be carried out in accordance with "this Regulation", internationally agreed protocols and the test methods described by the OECD when available. What we have here are vague recommendations, with frequent use of the word "should" and hardly any use of the word "must." We know from past experience that EFSA does not actually insist on the highest Codex Alimentarius standards anyway, for example by accepting evidence based on the use of surrogate proteins, and not insisting on tests on cooked or uncooked whole GM foods.

(v) CHOICE OF COMPARATORS. It is fully accepted in the Codex Alimentarius and OECD Guidance documents that all tests of GM materials MUST involve comparisons with non-GM counterparts or isolines. otherwise the results will be meaningless with respect to GM effects. We are greatly concerned that under "Comparative analysis" in the Draft Reg there now appears to be leeway in the choice of "the conventional counterpart" and additional comparators. Our reading is that a GM counterpart or "original event" can now be used -- rather than the isoline or variety from

which the GM plant was bred. This would be in clear breach of international protocols.

(vi) SURROGATE PROTEINS. Under "Toxicology" it is proposed to allow "testing of newly expressed proteins" without any instruction or requirement that they have to be isolated or derived from the GM plant itself. Under "testing of newly expressed proteins" (1.4.1) the new regs say that the tested protein "shall be equivalent to the newly expressed protein as it is expressed in the GM plant." The use of "surrogate proteins" in past research has been a major scandal, and applicants have been allowed to get away with it over and again. This is bad science, and scientific fraud is inevitable -- with potentially dramatic consequences for public health.

(vii) INSERTIONAL MUTAGENESIS. We can find no mention of this in the Draft Reg, although it is predicted on theoretical grounds and demonstrated in GM plants already in cultivation. Under "molecular characterization" there is no requirement for information on the effect of the GM process on the genome of the recipient plant (insertional mutagenesis.) There is no request or instruction for applicants to LOOK FOR insertional mutagenesis. This is a major defect, again with safety and health implications.

(viii) ANTIBIOTIC RESISTANCE MARKER GENES. In the text, we can see no requirement that ARMs (antibiotic resistance marker genes) MUST be removed after initial plant breeding. All the EC appears to insist upon is this: "The risk assessment may be facilitated if the presence of inserted DNA not essential to achieve the desired trait is minimised." (See also Annex II, 2.1) That is hardly a tough statement of policy or intent, and there are public health implications.

(ix) MOLECULAR CHARACTERIZATION. There are a number of major deficiencies in the Draft Reg. Under "Hazard Identification" there is no requirement for information on the donor organism, its safety or health effects, allergenicity and so forth. As indicated above, the effect of the GM process on the genome of the recipient plant (insertional mutagenesis) MUST be demonstrated. Relating to DNA, applicants can submit a sequence as it was "intended to be inserted" -- which may of course turn out to be quite unlike the sequence actually contained within the commercialised GM plant. And when it comes to the expression of inserts, the text says that where tissue- specific promoters have been used, information "may" be requested on the expression of target genes in other plant parts relevant for risk assessment. That means that such information may also NOT be requested.....

(x) SUBSTANTIAL EQUIVALENCE. Under 1.3.2.1. (Description of the protocols for the experimental design, (a) Principles of experimental design) there is a fascinating and protracted discussion on how an applicant is supposed to demonstrate that a GM variety is substantially different and substantially equivalent to its "counterpart", all at the same time. Please forgive us for saying so, but this is like something from a comedy show, and is a perfect example of science in the mad-house. In any case, there is now overwhelming evidence that GM varieties are substantially different from their isolines.

(xi) SAFETY STUDIES INVOLVING ANIMALS. The Draft Regs appear to accept that 90-day rodent feeding studies need not be designed "to detect effects on reproduction or development, other than effects on adult reproductive organ weights and histopathology." Why not? Reproductive effects are of massive potential significance, and the effects of reproductional toxicity should be looked for during and after the first generation. Applicants are given the option to test the whole food and feed beyond a 90-day rodent feeding study, "where appropriate." It is beyond belief that any applicants will ever do this, if they are given the option not to. Given what we already know about toxic effects arising from the consumption of GM feed, full lifetime studies on rats should be mandatory. There is also no requirement even for short-term livestock feeding studies (1.4.4.4. Interpretation of relevance of animal studies) -- although the Draft Regs say they may be considered, on a case-by-case basis and be hypothesis-driven. Again, there is no chance whatsoever that any such studies will be done voluntarily. There should be a clear requirement for lifelong feeding studies on "target animals" -- ie those which will consume GM materials for the whole of their lives. (1.6.2) Also there is very little in the document about the indirect effects of herbicide residues arising from the planting of RR or other herbicide tolerant GM crops,

although by law these effects must be identified and revealed. This is another major defect. Again, there is no requirement placed on applicants to look for the synergistic or combined effects of herbicide treatment and transgenes on either nutritional value or toxicology. We already know, for example, that certain transgenic rice varieties have reduced nutritional value in addition to other defects.

(xii) DEPENDENCE ON INDUSTRY STUDIES. Under 1.4.5. (Conclusion of the toxicological assessment) there is mention of various "adverse effects" that might be identified in feeding and other studies. But it is extraordinary that the EC proposes that all of the assessment of the safety studies should be done by the applicant, with no independent involvement or verification studies. Does the EC really think that an applicant is going to point out potential adverse effects in his toxicology studies? The invitation in 1829/2003 for independent reviews of the raw data, or for peer-reviewed studies to be submitted, has now been ditched. There are two problems here. The first is that EFSA and the EC assume the honesty of Monsanto, Syngenta and other corporations which are renowned for their expertise in scientific fraud. The second is that the research which the regulators accept as honest is almost always non-replicable, since the seed and feed owners will not permit truly independent research teams to use their materials for repeat or improved experiments. In spite of frequent invitations, the Commission has consistently refused to address this issue, although it was invited to do so by the Environment Council on 4th December 2008. In our view all industry-sponsored research on GM safety must be assumed as designed to produce "convenient" results, until it is independently verified.

(xiii) ANALYSES OF RAW DATA. There is no requirement in the Draft Regs for an applicant to release or reveal his test data for peer group or public review -- he is only asked to "justify his conclusions" or to "consider" or "evaluate" his data. That is a nonsensical state of affairs. This is a very controversial area, given that EFSA connives in the "protection" of data and experiment information if applicants claim it under the "commercial in confidence" rules. There is secrecy and censorship on a scale that is entirely inappropriate, and where there is no threat whatsoever to intellectual property rights. It is unacceptable that interested parties have to resort to the courts in order to achieve public access to experimental data and to facilitate peer review by independent scientists. Under 3.2.2.2. (Information of variation of constituents from databases) we find the following: "Based upon the considerations above, the applicant shall establish whether the differences and/or lack of equivalence observed are to be considered relevant for further consideration in the risk assessment process or if the difference and/or lack of equivalence does not raise safety concerns". This allows applicants to argue that observed differences between test animal groups are "not biologically significant" even if they are statistically significant. We therefore ask for the following to be added: "Statistically significant differences shall always raise safety concerns." Furthermore, we condemn the common practice of EFSA in accepting without question the data analyses conducted by applicants, while subjecting independent analyses of the same data to sceptical and even hostile scrutiny. This can only lead to accusations of complacency, connivance in defective science, and lack of objectivity in the "facilitation" of GM approvals.

(xiv) POST-MARKET MONITORING. "When necessary, a proposal for post- market monitoring regarding the use of food for human consumption and/or the use of feed for animal consumption shall be submitted in accordance with Annex III." The Annex allows the applicant and EFSA to say "we have monitored past crops that have now been combined into a stacked event -- so monitoring of the stacked event in the field and in the food chain is unnecessary." That is unacceptable to us, for the reasons outlined above. Annex III also implies that, as long as a Post-Marketing Proposal is submitted, it is permitted to market a product even if "it is not possible to address remaining uncertainties", if "the relevance and intensity of effects and side-effects ... are difficult to predict", and if "potential side-effects are identified but cannot be studied in ... the safety assessment". In other words, the company need not bother to test safety thoroughly, as long as it will continue to collect some data (unspecified) about the general public and any animals that are given the GM food / feed, in order to see whether people or animals are becoming ill in large numbers. This again is irresponsible, and completely unacceptable.

(xv) HEALTH IMPLICATIONS. We see signs in the Draft Regs that the Commission and EFSA are making unjustified assumptions about the safety of GM crops and foods. For example, on the matter of allergenicity, there is a watering down of long-established requirements to show that GM plants are not harmful. Now we see the use of vague terms such as "depending on the available information"..... with no requirement for studies to demonstrate safety in use. Also, there seems to be a conflation of Nutritional assessment and Exposure assessment. The Draft Regs say: "If possible, the applicant shall identify and consider particular sections of the population with an expected high exposure and shall within the risk assessment (stet)." There is a drafting error here -- but in our view there should be a strict requirement for a written analysis of sections of the population that might be at increased risk from the consumption of GM food or animal products from GM-fed animals -- for example, vegetarians or those with coeliac disease might be subjected to high levels of GM soy intake.

(xvi) RESEARCH BLOCKING. In Annex IV we find these words: Applicants shall provide "samples of the food and feed and their control samples of a type and amount to be specified by the CRL for the specific application for authorisation." Also: "The applicant shall provide information as regards the place where the reference material can be accessed. This shall be accompanied by adequate information demonstrating that the availability of the reference material will be maintained throughout the period of validity of the authorisation." Generally, CRL only requires enough reference material for verification of the GM event, and for confirming the efficacy of test methods etc. There is NO requirement for applicants to provide adequate quantities (of GM varieties and their isolines) for independent verification or repeats of their safety experiments and feeding trials. So effectively the applicants retain full control of their reference materials and have to make no commitment to provide extra material either for the EC or for anybody else. As indicated in (12) above, this means that all of their experiments are NON-REPLICABLE -- and on that basis alone they should not even be considered by the regulators as valid "science." What do the Commission and EFSA propose to do about this blatant and on-going abuse of scientific ethics?

4. The "competent authorities" for field trials and cultivation of GM crops are the national Environment Ministries of the EU Member States; the competent authorities for feed and food are usually the Agriculture and Health Ministries.

5. GM crops contaminate the global food chain, causing economic losses, world-wide product recalls, national market shut-downs, and billion-dollar lawsuits. Records are kept on the international GM Contamination Register web site at http://www.gmcontaminationregister.org

6. Here is the full text of the letter from the scientists to the President of the European Parliament Jerzy Buzek, with notes and appendix: The signatories also sent similar letters to the President of the European Council Herman Van Rompoy, to the President of the European Commission Jose Manuel Barroso, and to the European Commissioner for Health and Consumer Policy John Dalli.

Formal Protest from Scientists:
Commission Regulation on Implementing Rules for GM applications and assessments

Open letter to the Jerzy Buzek, President of the European Parliament

22 February 2010

Dear Professor Buzek,

We write to you as a group of concerned European scientists. Purely by chance, we have found a new Draft EC Regulation (1) on the WTO web site, and we respectfully ask you (a) to take this as a formal protest relating to the content of that regulation, and (b) to bring this protest to the attention of the full Parliament at the earliest opportunity.

We gather that this Regulation has been drafted by the Commission with great secrecy, submitted to the WTO under its conformity assessment procedure, and is due to be brought into law in May of this year without any consultation with the public, NGOs or consumer groups, and even without discussion among the "competent authorities" who are responsible for GMO risk management in the various countries of the EU. That causes us very great concern, even though the Commission might have followed the correct procedures for bringing in an "Implementing Regulation".

Having undertaken a quick analysis of the Draft Regulation (which is long enough at 66 pages to require protracted examination!), we see a number of significant and worrying trends. It appears to us, at the outset, that this document is designed to speed up the regulatory / approvals process, in response to pressure from the US administration and the WTO. It also appears to represent a step along the way towards "harmonisation" or "synchronisation" of the approvals process on both sides of the Atlantic, by building in a whole range of measures which will ease the way for "simpler" and cheaper applications to come forward. This is to the considerable benefit of the multinational corporations, especially with respect to their plans for a new generation of "stacked" GM varieties, but we fear that it pays scant regard to the safety of animals and human beings, or to the protection of the environment.

What we see in this Draft Reg document is a further move away from sound, independent science (and evidence-based policy) and a lurch towards a formal acceptance of a ruling hypothesis -- namely that GM crops and foods are harmless. There are few signs of checks and balances in the system as it is outlined, and hardly any options for the replication of scientific experiments. Since non-replicable science MUST be considered unreliable and even fraudulent, this is a move towards connivance in fraud. And that, in our view, is a very serious matter.

We have a whole range of detailed comments on the text of the Draft Regulation, which we are happy to submit to you. We summarize them in Annex 1 below.

It is our firm belief that in this Draft Regulation the Commission far exceeds its implementing powers, as indicated in our Annex, for the most part through subtle changes of wording, and sometimes through omissions and explanations which are distorted. There are a number of new assumptions about GM safety which are NOT scientifically justified. There are also many policy changes which should have no place in an Implementing Regulation. The Draft Regulation fails to take account of the extensive recent literature relating to the harmful effects of GM, and it must therefore be redrafted.

We gather that this Draft Regulation will shortly come before Parliament and Council for approval. We urge you, in view of the very great importance of this matter, to refuse approval and to insist upon an extended period of consultation, during which due consideration can be given (a) to any detailed comments you have received relating to the full text of the document, and (b) to the 16 vital scientific issues which we have raised in this letter.

We look forward to your confirmation that the draft text of this Regulation will be rejected, and then reconsidered and amended to take account of these valid concerns. We do not accept that this cannot be done at this late stage in the process, since the process is entirely under your control.

We hope to hear from you in the near future. We are also sending this protest to your colleague Mr Herman Van Rompuy, President of the European Council.

Yours sincerely,

Dr Brian John
Dr Jose Ramon Olarieta
Prof Brian Wynne
Dr Mae-wan Ho
Prof Jose L. Domingo
Prof Bob Orskov

Prof. Enric Tello
Dr Eva Novotny
Dr Irina Ermakova
Dr Naheeda Portocarero
Dr Arpad Pusztai
Prof Marcello Buiatti
Dr Susan Bardocz

Affiliations and qualifications available on request.

Reference (1) Draft COMMISSION REGULATION on implementing rules concerning applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Regulations No (EC) 641/2004 and (EC) No 1981/2006 (Text with EEA relevance)
http://members.wto.org/crnattachments/2010/tbt/eec/10_0030_00_e.pdf

APPENDIX: SIGNIFICANT SCIENTIFIC AND SAFETY CONCERNS

[The full text of the appendix may be found in note 3 above.]

7. Here is the text of the two letters sent to the European Commissioner for Health and Consumer Policy John Dalli, (who gave the green light for the cultivation of GMO potatoes yesterday 2 March 2010):

John DALLI
European Commissioner for Health and Consumer Policy
European Commission
B - 1049 Brussels

cc President Manuel Barroso

Dear Commissioner Dalli,

Commission Regulation on Implementing Rules for GM applications and assessments

As you will be aware, on 12th January a Draft GM Regulation (1) was placed onto the WTO website under its conformity assessment procedure, and is due to be brought into law in May of this year. Because of the complex procedures within the EU, this has been done without any consultation with the public, NGOs or consumer groups, and even without discussion among the "competent authorities" who are responsible for GMO risk management in the various countries of the EU. We do not think there has been any discussion within the Parliament either. That causes us very great concern, even though the Commission might have used comitology rules and followed the correct procedures for bringing in an "Implementing Regulation".

We are a group of scientists with long experience in the GM field, and we are so worried about the content of this Draft Regulation that we have brought our concerns to the attention of Professor Buzek, the President of the Parliament, and Mr Van Rompuy, President of the European Council. We are now also raising these concerns with you and President Barroso, and we respectfully urge you to hold back the Draft Regulation for careful scrutiny by individuals other than the national representatives and EFSA staff who have drafted them. The drafting process has been too tightly controlled, and we believe that if the safety and health of the people of Europe are to be safeguarded, much of the text needs to be modified.

The grounds for our protest are as follows:

1. We understand that the Commission and EFSA staff who have done the drafting work have promoted the draft regulation as "tightening up" or strengthening the precedures for the assessment of GM applications. With all due respect, if you read the Regulation for yourself you will

see that it does nothing of the sort. In fact, it waters down the application requirements and assessment procedures to such an extent that some applications can now go through under a simplified procedure with virtually no scientific scrutiny or risk assessment along the way.

2. There are a number of scientific grounds for concern, which we have already spelled out for Professor Buzek and Mr Van Rompuy, and which we also append below. These are very serious matters, and it appears to us that EFSA and Commission civil servants have -- for whatever reason -- slipped from the high scientific standards which we have a right to expect of them, and have in the process placed the safety of the people of the EU at risk. We will appreciate it if you will examine our points very carefully -- and we will welcome the opportunity to discuss these further with you and your staff.

3. We believe that another reason for the "slippage of standards" in this Draft Regulation is the desire -- on the part of your civil servants -- to put in place a "fast track approvals process" for political or diplomatic reasons, in order to appease the United States government and the WTO. The motive is, no doubt, to demonstrate that in the EU there is no GM-related "restraint of trade." That is understandable, given the outcome of the famous GM ruling of a few years ago! However, in seeking to achieve this political objective, the careful regulatory regime for which Europe is justly renowned has been dismantled and undermined -- and this cannot have been the intent of the Commission.

4. What we see over and again in the clauses of the Draft Regulation are subtle -- and sometimes blatant -- changes of POLICY relating to GMOs. Again, this might not have been the Commission's intention, but those who have drafted the text have not restricted themselves to "implementing rules". They have gone far beyond that, and that is why we have claimed in our letters to Professor Buzek and Mr Van Rompuy that the Commission -- which has to take responsibility for this -- has exceeded its powers. You need to read the text carefully in order to appreciate this -- and if you wish we will be happy to itemise for you nine distinct and discernible policy changes.

5. Finally, we consider that this Draft Regulation goes dramaticallyagainst the letter and the spirit of the decisions made by the Environment Council at its meeting on 8th December 2008. That meeting stressed the need for greater transparency, greater accountability, less secrecy, more cooperation between EFSA and member states and competent authorities, and an enhanced role for independent science and peer review. On every one of those issues, the Draft Regulation goes in the opposite direction, greatly enhancing the power of EFSA to treat applications more or less as it wishes and to make deals with the applicants for GM approvals. That is a dangerous and even sinister trend, and we trust that the Commission will not wish to be associated with it.

Please, therefore, withdraw this Draft Regulation for a period of calm reflection and careful scrutiny. We and many NGOs and consumer groups will, we are sure, be prepared to contribute constructively to this process.

We look forward to hearing from you on these matters. By the way, we understand from your office that you are due to meet Mr Hilary Benn, our Secretary of State for the Environment and Rural Affairs, on Monday. You will have many things to talk about! But we hope that you might be able to bring the matters covered by this letter to his personal attention.

Yours sincerely,

Dr Brian John, Dr Jose Ramon Olarieta, Prof Brian Wynne, Dr Mae-wan Ho, Prof Jose L. Domingo, Prof Bob Orskov, Prof. Enric Tello, Dr Eva Novotny, Dr Irina Ermakova, Dr Naheeda Portocarero, Dr Arpad Pusztai, Prof Marcello Buiatti, Dr Susan Bardocz, Dr. Christian Vélot, Prof. G-E Seralini, Dr Carlo Leifert, Prof Philip Bereano

[The above letter includes the same Appendix to the letter sent to the President of the European Council, Jerzy Buzek (see note 2 above)]

The scientists sent a follow-up letter to Commissioner Dalli on 26 or 27 February 2010:

John DALLI
European Commissioner for Health and Consumer Policy
European Commission
B - 1049 Brussels
(Belgium)

Email: cab-dalli-webpage@ec.europa.eu
john.dalli@ec.europa.eu

cc President Jose Manuel Barroso

Dear Commissioner Dalli,

Internal Consistency of Commission GMO Regulations:
Commission Regulation on Implementing Rules for GM applications and assessments

Further to our letter of 26th February, we have had further discussions about the implications of the Draft Regulation (1) which was notified by the Industry and Enterprise Directorate to the WTO and EEA on January 12th 2010. We understand that this document is a simplified one suitable for consumption by economists and others with a limited knowledge of the health, safety and environmental implications of what is proposed.

However, quite apart from our concerns of a scientific nature, relating to the proposed application and assessment procedure, and the manner in which the drafting team has exceeded its powers by introducing policy changes into an implementing measure, we wish to raise one crucial point as a matter of urgency.

If this new regulation is signed by Mr Barroso in the near future, and brought into force in June 2010, is it not the case that all future related regulations (arising from the on-going review of EFSA guidance to operators with regard to GMO applications and authorisations) will have to be substantially equivalent to it? It is our understanding that there must not be internal contradictions or inconsistencies in EU Directives and regulations.

Thus we are concerned that a seriously flawed Regulation might now be brought into force precipitately, simply to suit the United States and the WTO, without adequate scrutiny as to its legality and concerning those health and safety issues that are in the domain of your Directorate.

We ask you therefore for an assurance that this Regulation will NOT be signed off in the near future, until all of the issues raised by us and other interested parties have been thoroughly explored with a view to finding a consensus.

Thank you for your consideration in this matter. We look forward to hearing from you.

Yours sincerely,

Dr Brian John, Dr Jose Ramon Olarieta, Prof Brian Wynne, Dr Mae-wan Ho, Prof Jose L. Domingo, Prof Bob Orskov, Prof. Enric Tello, Dr Eva Novotny, Dr Irina Ermakova, Dr Arpad Pusztai, Prof Marcello Buiatti, Dr Susan Bardocz, Dr. Christian Vélot, Prof. G-E Seralini, Dr Carlo Leifert, Prof Philip Bereano

NOTE:

(1) Draft COMMISSION REGULATION on implementing rules concerning applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No

1829/2003 of the European Parliament and of the Council and amending Regulations No (EC) 641/2004 and (EC) No 1981/2006 (Text with EEA relevance) EU notification G/TBT/N/EEC/304 http://members.wto.org/crnattachments/2010/tbt/eec/10_0030_00_e.pdf

8. The press release is quoted in full in note 1 above.

9. See note 1 above.

10. Mairéad McGuinness MEP of Fine Gael has lobbied the Parliament and Commission to legalise the cultivation of GM pharmaceutical crops that could contaminate the Irish and European food chains with industrial chemicals and drugs.

11. European Commission gives green light to genetically modified potatoes
Public let down by EU's new consumer chief, says Friends of the Earth Europe.
Friends of the Earth Europe press release, 2 March 2010:
http://www.foeeurope.org/press/2010/Mar02_EC_gives_green_light_to_GM_potatoes.html

EC forces through "bad decision" on GM industrial potato and ignores health risks
Press release, GM Freeze (UK), 2 March 2010:
http://www.gmfreeze.org/page.asp?id=420&iType=

EU commission approves cultivation of first GM crop in 12 years.
EU Observer, 3 March 2010: http://euobserver.com/9/29598/?rk=1

12. See:

- GM-free Irish label good for business: Added value, increased market share, better branding and unique selling point: the most credible GM-free food brand in Europe. GM-free Ireland Network press release, 17 November 2009: www.gmfreeireland.org/press/GMFI46.pdf

- GM-free production: a unique selling point for Ireland - the food island. 47-page briefing with GM-free market survey, 17 Nov. 2009: www.gmfreeireland.org/GMFI-briefing-3.pdf

- The business case for Ireland's GM-free label. Press conference video with Richard Corrigan (Michelin star chef and TV host), Darina Allen (Slow Food Ireland, Good Food Ireland, Free Choice Consumer Group, Artisan Food Forum, and the Farmers Market movement), Malcolm Thompson (Irish Cattle and Sheepfarmers Association), Evan Doyle (the Taste Council, Organic Trust and Euro-Toques Ireland), Dr. John Fagan (Cert ID), and Michael O'Callaghan (GM-free Ireland): The video may be seen on the GM-free Ireland home page at www.gmfreeireland.org