

OPEN LETTER 23rd February 2010

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

For the personal attention of President Jerzy Buzek, European Parliament, Brussels
Email: Head of Cabinet maciej.popowski@europarl.europa.eu
22nd 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,

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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

1. 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.

2. 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.....

3. 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 they 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)

4. 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.

5. 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 isolate or variety from which the GM plant was bred. This would be in clear breach of international protocols.

6. 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 over again. This is bad science, and scientific fraud is inevitable -- with potentially dramatic consequences for public health.

7. 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.

8. 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.

9. 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.....

10. 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.

11. 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.

12. 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.

13. 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.

14. 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.

15. 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.

16. 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?

