GM Food & Feed - Comments from the Public

Comments received on Maize 1507:

Organisation: private person

Country: Finland

Comment on Opinion (Background and conclusions):

I give my opinion as private person. I have worked over 20 years as an oat and pea breeder in Finland, at first at state plant breeding institute, and then at private plant breeding organisation owened mainly by the state of Finland. I released 3 pea and 6 oat varieties in Finland, Norway and Island during my last 10 plant breeding years. Then I was put out from plant breeding work. There has happend a big decrease in plant breeding in Finland at least 10 yaers. During the last 10 years about 2/3 of the plant breeders have loosed their work. There is now 5 plant breeders breeding the agricultural plants for the 2 million ha of field in Finland, and only one or two persons breeding the horticultural plants. At the same time there are over 1000 persons making other agricultural research, and hundreds of persons making biotechnologycal research in crop plants. Nobody is wondering this situation. EU is controlling the covenmental money putting it to the normal traditional safe plant breeding and plant breeding is put to the hands of commercial men, who do not understand anything about plant breeding. EU is giving money only to fine biotechnologycal research and direct support to farmers. Traditional plant breeding is not supported by anybody.

EU is controlling and making new directives for mycotoxin contents, traces of pesticides,but at the same time it is releasing GMO maize, which kills insects and which can be treated by harmfull pestices. New directive for baby food is saying that there must not be any treases of pesticides in baby foods. At the same time EU is supporting usage of pesticides by marketing GMO maize. The situation is stupid.

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Organisation: GeneWatch UK

Organisation type: Non Profit Organisation

Country: United Kingdom

Comment on Opinion (Background and conclusions):

GeneWatch UK is a not-for-profit policy research group that monitors scientific, policy and regulatory developments in genetic technologies from a public interest, environmental safety and animal welfare perspective. We welcome the opportunity to comment to the Commission as it considers Pioneer Hi-Bred's application to use GM maize 1507 for food use.

We have found it impossible to fit our comments in the boxes but hope you will be able to understand how the numbers in the summary below fit with the numbers in the text following although the text does not apply to the box titles.

We would be interested to know the legal basis of the restriction on length of public comment and why it has been imposed.

Comment on Annex A (GMO panel risk assessment report):

Our key comments, which are expanded upon below, are that:

1. the EFSA's scientific panel's conclusion that a post-marketing monitoring plan for food/feed is not needed is wrong and does not take into account the need to test assumptions made in the risk assessments;

2. the EFSA's scientific panel's conclusion that the scope of the monitoring plan provided in relation to environmental impacts is adequate is wrong because a 'plan' is not defined and is not expected to be until 2 years after approval under 2001/18 is given. It is questionable whether accepting a plan to produce a monitoring plan is lawful under Directive 2001/18 or Regulation 1829/2003;

3. no information is provided in the application about the effect, if any, on levels of naturally occurring allergens in maize.

4. the application itself does not fulfil the requirements of Article 27 of Regulation 1829/2003 because it only applies to food uses. Where a product is likely to be used as both food and feed, a single application and decision by the Community is required. Therefore, if the approval is given it is questionable whether it would be lawful; and

5. in relation to 'other relevant factors' in coming to its draft decision under Article 7 (1), the Commission should consider:

    the views of European citizens and their concerns over the potential for long-term harm to human health, in deciding whether it is acceptable for there to be no monitoring for effects on human or animal health;
    the damaging impacts on consumer confidence in the EC if unintended effects subsequently arise from the consumption of 1507 maize and no attempt to undertake monitoring was conducted;
    that the regulatory approach taken by the EC is intended to be precautionary. Absence of evidence of harm should not be equated with evidence of absence.

Comment on Annex B (Cartagena protocol):

3 Naturally occurring allergens in maize

Maize is not a commonly associated with allergenicity but cases have been reported. As recorded in the OECD's consensus document on maize , two major food allergens have been reported. There does not appear to have been any investigations conducted by the applicants to determine whether the genetic modification has caused alterations in the amounts of these proteins produced.

4 Requirements for a 'single opinion'

Article 27 of 1829/2003 in relation products likely to be used as both food and feed says:

1. Where a product is likely to be used as both food and feed, a single application under Articles 5 and 17 shall be submitted and give rise to a single opinion from the Authority and a single Community decision. (emphasis added)

2. The Authority shall consider whether the application for authorisation should be submitted both as food and feed.

In the case of maize 1507, which is intended both for food and feed, only an application for food use has been made under 1829/2003. There are no provisions that state that applications made under 2001/18 can substitute for this. The EFSA has given an opinion on the food uses and a separate opinion for import, feed and processing for 2001/18. This will result in two separate Community decisions being taken under different regulatory routes and of questionable lawfulness in relation to food and feed uses. In the case of adverse impacts arising, this could be of considerable significance.

Comment on Annex C (Labelling) :

5 Other relevant factors

In making its draft decision under Article 7 (1) or Regulation 1829/2003, the Commission can take into account 'other relevant factors' which have not been considered by the EFSA. GeneWatch believes that there are several additional issues that the Commission should consider rather than simply endorsing the EFSA's recommendation. Given the political sensitivities surrounding GM food, it is vital that the Commission takes this seriously and gives due weight to the views of European citizens.

- European citizens remain ambivalent about GM crops and food. The 2002 Eurobarometer results showed that: 'A majority of Europeans do not support GM foods. These are judged not to be useful and to be risky for society. For GM crops, support is lukewarm, while they are judged to be moderately useful they are seen as almost as risky as GM foods.' A range of other research using qualitative methods underlies these findings and highlights concerns about long-term impacts on health and the environment and also that people do not see any particular benefits from the current generation of GM crops. Making a presumption that risk assessments for food/feed have been complete and therefore monitoring is not needed, is unlikely to be a view that is widely shared, particularly in the light of experiences with 'mad cow' disease and other food scares.

- The public has deep concerns about the behaviour of Europe's bureaucracy in relation to democratic processes and financial probity. Decisions in the sensitive field of GM foods which do not give weight to the views of the European public, will further erode confidence. If, having accepted the positive opinion from the EFSA, Member States cannot agree on whether to approve maize 1507, the Commission may step in and give a marketing consent. If the views of European citizens have not been properly taken into account in the decision making process, cynicism and mistrust is likely to increase and political divisions will widen. This is a dangerous situation for the European Communities.

- The regulatory approach taken by the EC in relation to GMOs is intended to be precautionary. In a precautionary approach, absence of evidence of harm should not be equated with evidence of absence but this tends to be the case in the way in which the 1507 risk assessment is presented by Pioneer Hi-Bred and interpreted by the EFSA. The Commission should require the EFSA to conduct a more precautionary approach which highlights the areas of uncertainty and absence of information, which will then provide a much better platform for decisions about whether to proceed or under what conditions.

Comment on Annexes D1, D2, D3 (analytical method, sampling and extraction):

1 Post-market monitoring for food/feed safety

In its opinion, the EFSA's scientific panel concludes that no data have emerged in the risk assessment to indicate that the maize line is less safe than its non-GM comparators. The Panel agrees with the applicant that monitoring is not needed because the guidance document only supports monitoring

where there is some kind of intentional nutritional change to the GMO. Here both the Panel and the Guidance fail to understand risk assessment and its limitations.

In the GM field as elsewhere, it is becoming increasingly clear that the results obtained by 'science based' risk assessment are highly sensitive to the particular questions that are asked, the way that they are posed, and the assumptions that are made in answering them. Assumptions have to be made and judgements exercised including about what kinds of harm to include, what level of uncertainty is acceptable in estimates of likelihood of harm arising and whether experimental studies will accurately reflect the situation in the 'real world'. As well as uncertainty in the various parameters and their measurements, there may also be completely unexpected outcomes. This will be true however assiduously a risk assessment is undertaken and is not a criticism of those involved but demands review and testing.

Annex VII of Directive 2001/18 recognises this in relation to monitoring where it explains that the objective of monitoring is to:

- confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the e.r.a. are correct, and
- identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the e.r.a. (emphasis added)

The EFSA's Panel report itself includes these many judgements concerning the occurrence and impact of potential adverse effects. Examples, with added emphasis on where opinion, not data, are relied upon, include

"Evidence that the maize genomic DNA was contiguous with the flanking regions of the insert was not provided. The possibility of undetected deletions at the insertion site caused by the transformation process has been considered. The Panel is of the opinion that it is very unlikely that putative deletions or rearrangements at the insertion locus would result in undiscovered adverse effects." (p7)

"Statistically significant differences were occasionally observed in some GM plants, for example increased overall levels of carbohydrates and decreased levels of fat in forage of maize line 1507 (both sprayed and non-sprayed) in the 2000 season. However, there were no differences that were consistently observed over years and at each location". (p8)

"The Panel is of the opinion, however, that such additional information would not add value to the data that had already been provided, given, among other things, the high variability of the levels of some compounds like selenium and DIMBOA, due to environmental conditions or the stage of plant development". (p9)

"It is therefore unlikely that this extension would affect the functional, toxicological, or allergenic properties of the protein". (p11)

"Allergenicity of the whole crop could be increased as an unintended effect of the random insertion of the transgene in the genome of the recipient, for example through qualitative or quantitative modifications of the pattern of expression of endogenous proteins. This issue does not appear relevant to the Panel since maize is not considered a major allergenic food and possible over-expression of any endogenous protein that is not known to be allergenic would be unlikely to alter the overall allergenicity of the whole plant. The same considerations also apply for exposure by inhalation". (p15)

Comment on Annex E (Monitoring plan):

In drawing attention to these kinds of judgements in the section above, GeneWatch is not suggesting that the Panel is necessarily wrong or has not brought its best efforts to bear, but that it might be wrong and it is this reality that monitoring seeks to address. As such, monitoring should help inform subsequent deliberations by improving the scientific knowledge base. From this perspective, a case-specific monitoring plan of food/feed safety which seeks to take a rigorous scientific approach might, for example, include:

- tracking of a sub-set of the population who are known to be sensitive to the allergens in maize;

- regular sampling for compositional analysis to establish that statistical differences reported in the risk assessment are not consistent;

- following a population of animals and people consuming the maize to determine if horizontal gene transfer takes place in the intestine.

2 Adequacy of general surveillance monitoring plan

Plan: a series of steps to be carried out or goals to be accomplished; "they drew up a six-step plan"; "they discussed plans for a new bond issue" http://www.wordreference.com/definition/plan

The proposal for a monitoring plan for general surveillance which was accepted as adequate by the EFSA's scientific panel it is not a monitoring plan but a plan to establish a monitoring plan. The monitoring plan, with goals and steps to reach its objectives, will not be available until two years after receiving consent to market 1507 maize under Directive 2001/18 . For example, it says:

"We expect to be able to organise such a coordinated plan for general surveillance of animal feed products within two years after receiving the consent for placing on the market (import) of 1507 maize. (1.3.2)

However there is no accompanying 'coordinated plan' at all, as is quite clear from the following section which says:

"Therefore, we propose to discuss the facilitation of the observations of the market introduction (imports) of 1507 maize and of the interpretation of these observations with respect to human health or the environment with the relevant trade associations representing animal feed manufacturers, in consultation with national Competent Authorities and associated bodies, as part of the implementation of the plan for general surveillance of 1507 maize products".

Nowhere are the 'observations' that might constitute a 'plan' described.

GeneWatch does not believe that such a non-existent plan can be considered lawful within the meaning of Regulation 1829/2003 or Directive 2001/18.

Organisation: Consiglio dei Diritti Genetici

Organisation type: Non Profit Organisation

Country: Italy

Comment on Annex A (GMO panel risk assessment report):

Point 2.2.2

GMO Panel writes, "analysis of the sequences adjacent to the insert of fragment PHI8999A revealed DNA fragments that correspond to small segments from PHI8999A, including incomplete sequences from the pat gene, the maize ubiquitin promoter and the mannopine synthase terminator from Agrobacterium. Furthermore, different fragments of chloroplast DNA and a number of sequences with similarity to retrotransposons are also present in the border region of the insert.....PCR analyses indicated that the fragments in the flanking regions can also be found in the recipient line (Hi-II). No data documenting the intactness of the insertion site were shown. Therefore, a direct comparison of the insertion locus and the respective site in the recipient plant is not possible." and concludes that, "There is, however, no indication that such a deletion produces any phenotypic effect in the transformed maize line (see section 3)".

In conclusion, molecular characterization of the maize insert 1507, showed the presence of important insertions of unexpected sequences at the insertion locus, including sequences not present in PHI8999A. We retain, that these data don't allow concluding that the genotypic alterations, observed or potential, don't produce any phenotypic effect in the transformed maize line. In order to better investigate this hypothesis, we consider that should be necessary to apply profiling technologies (transcriptomics, proteomics, metabolomics).

Point 3.2.2

It seems to us that there are consistent statistically significant differences between compositional analysis of maize 1507 and control hybrids.

Indeed, in Study number PHI98-09-RA-NGLP-012 (experimental study 1998/1999), level of calcium is out of the ranges published in literature; level of potassium is higher and level of manganese is lower than level of control kernels in 1999.

Moreover, there are consistent statistically significant differences between level of fat – excepted palmitic acid – in maize 1507 and control hybrids. There are also differences between levels of cysteine, methionine, glutammic acid and threonine and ranges reported in the literature.

It seems clear that the metabolic path of maize GM has been modified. It seems necessary to us verify the validity of the experiment and the experimental data.

Point 4

It seems to us that the design of feeding study is not well focussed, and is not adequate to demonstrate the safety of the GM maize 1507 for human food.

There is a list of significant differences between the various biologically meaningful parameters of rats fed GM maize diets and proper controls, as the GMO-Panel reported in point 4.2.4.1.

It would be impossible for anyone to state that all the statistically significant differences are also biologically relevant, however, it seems that the opposite cannot be said either without proper follow up studies.

With reference to the data reported in the opinion, it seems to us that additional feeding studies should be conducted before bringing out maize 1507 for human consumption.

Point 5.2.1.4

The notification do not cover cultivation, but, from our point of view, unintentional spilling could cause unintended effects that the GMO-Panel has not considered. We retain necessary to pose specific measures to minimize accidental spillage during transport and processing of maize grain.

Organisation: CLEAN(Cavan Leitrim Environmental Awareness Network)Ltd

Organisation type: Non Profit Organisation

Country: Ireland

Comment on Opinion (Background and conclusions):

PART 1 OF OUR SUBMISSION. PART 2 WILL FOLLOW IN SEPERATE FORM, AS WE ARE TOLD THAT OUR SUBMISSION IS TOO LONG. WE HAVE ALREADY SHORTENED IT. WE CAN NOT ACCEPT THAT THE LENGTH OF SUBMISSIONS IS SO RESTRICTED.

We do not accept the conclusions and recommendations to approve 1507 maize for the reasons outlined under the following headings.

Comment on Annex A (GMO panel risk assessment report):

3.2.2.

Compositional Analysis gives several examples of observed differences between 1507 maize and the non GM-control group. Here we see that under certain environmental and weather conditions 1507 can be significantly different to non GM maize. Effects of different environmental conditions on 1507 maize were not investigated or explained, and are not understood, nor were the possible consequences of observed higher or lower levels of individual components for human and animal health.

It does not suffice to say that statistically differences observed over years were negligible, if only one very different crop in a certain area at a certain time, or over some time, could have detrimental effects to human and animal health.

For the same reason we do not accept the content and message of the following paragraph, which confirms the above by basically saying that the composition of the GM maize under different environmental conditions is not wished to be known or investigated, nor are the potential differences to non GM maize. This can not be accepted, because 1507 maize will be grown under different environmental conditions, and if their influence on it is not investigated and compared to non GM maize, a vital part of information is intentionally not sought:

"During the Member State consultation under Article 6.4 of Regulation (EC) No. 1829/2003, it was suggested that additional compounds, including certain heavy metals, vitamins, and secondary metabolites, should be analysed. The Panel is of the opinion, however, that such additional information would not add value to the data that had already been provided, given, among other things, the high variability of the levels of some compounds like selenium and DIMBOA5, due to environmental conditions or the stage of plant development."

3.2.3. Agronomic traits and GM phenotype

If, apart from the slight differences, the 1507 maize performs agronomically so perfectly similar to its non transgenic counterpart, we ask why it is grown at all. There seems to be no difference in insect damage, yet it is "genetically modified to provide protection against specific lepidopteran pests". Has this claim be proven?

4.2.3.1. Cry1F and PAT proteins used for safety assessment

"Given the low expression levels of Cry1F in 1507 maize, the applicant decided to use a

trypsinised microbial analogue, MR872, of the truncated Cry1F protein expressed in maize line

1507 for safety testing."…"Taking into account all the evidence provided, the Panel is of the opinion that the trypsinised MR872 analogue is an appropriate substitute of the Cry1F protein expressed in 1507 maize for safety testing."

We do not accept this. We and other consumers can not understand the complex technical explanation for acceptance of using a substitute in safety testing given by the Panel, therefore we can

not check its validness. A lot of trust has to be put by the consumer in biotech and food scientists anyhow, but this is too much. As consumers we cannot accept that safety testing and risk assessment was not done using the actual protein expressed in 1507 maize. We do not accept approval of 1507 maize after such flawed safety assessment.

4.2.4.1 Subchronic oral toxicity

Here again we experience the tendency to explain away significant results as negligible. We believe this is fairly easy, if one wishes to do so, but not acceptable. In this case the first reason for explaining away a result, that "it was observed in one sex only" is ridiculous. Does exactly this not give rise to further questions and necessary examination?

Comment on Annex A (GMO panel risk assessment report):

4.2.5. Allergenicity

No testing was done on allergenicity. The examination of allergenicity is merely a desktop study comparing pieces of proteins. Even this has shown a relatively high percentage of identical pieces of the GM proteins of 1507 maize with known allergens.

We do not accept that an unpublished study is used to show that this is negligible, because such identities seem to exist also with non-allergenic proteins: "the Swedish National Food Authority found that for Cry1F, many six-amino acid identities with non-allergenic proteins existed (data not published)."

4.2.6. Nutritional assessment of GM food/feed

Results of nutritional tests are too broadly and vaguely described. No details of the actual measurements are given. We have no possibility to verify the conclusion that "results showed no significant differences between dietary treatments and indicate nutritional equivalence between the transgenic 1507 maize and the non-GM control."

Comment on Annex C (Labelling):

We wish to stress that it is untrue that "the genetic modification in 1507 maize does not give rise to any ethical or religious concerns."(p.2) GMO products are rejected by the European consumers not only for health and environmental fears, but to a large extent out of ethical, and religious, concerns.

"6. Specific instructions for storage and handling:

No specific instructions for storage and handling of 1507 maize are necessary for the placing on the market (import) of 1507 maize, and therefore grain and grain products of 1507 maize may be stored and handled in the same way as products from other commercial maize varieties."

We would have thought that storage instructions would have to include that the 1507 maize has to be strictly separated from non GM maize.

Comment on Annexes D1, D2, D3 (analytical method, sampling and extraction):

The detection methods presented and validated are designed to detect genomic DNA in ground unprocessed maize/seed. It has not been shown whether these methods will work with canned and other processed 1507 maize in food.

Comment on Annex E (Monitoring plan):

It is not acceptable that a general surveillance plan is proposed to be delivered only within two years after consent given! As we have seen with Sudan Red, and most recently with BT10 maize, major mistakes occur at the actual distribution stage of products.

No consent must be given without a general surveillance plan delivered!

In addition, a general surveillance plan can not be left to member states, or even trade associations and animal feed producers to be worked out with the notifier.