GM Freeze response to EFSA consultation on GM renewals guidance

Abstract

PAGE 1, LINE 16-18
"The applicants should also make a proposal, if appropriate, for amending or complementing the conditions of the original authorisation, *inter alia* the conditions concerning future monitoring". We recommend that this statement is removed.

It is not appropriate for applicants to suggest amendments to conditions or future monitoring – that is a job for regulators and politicians, with public involvement. Applicants, wider industry interests and the public can then comment on any proposals.

The record of industry to date is that they have not responded to EFSA-suggested improvements to Post Market Environmental Monitoring and have chosen instead to develop their own approach. It is extremely likely that if they did make proposals they would be aimed at protecting their shareholders rather than the environment, human and animal health.

WHOLE ABSTRACT
We also strongly recommend that the abstract provides a reminder of why the GMO Regulations exist. GMOs are the product of a technical intervention unlike conventional plant breeding. That intervention can produce unexpected and unintended changes to the composition of plants as well as the intended ones associated with the GM trait/s and the process of inserting genetic sequences. Applicants should be reminded that the whole organism should be assessed for direct and indirect negative impacts and risks rather than just for the intended changes produced by the genetic modification event.

We also urge the inclusion of data and assessments that address the impacts of growing and producing imported crops on the environment, human health, food security and livelihoods (socio economic impacts) in the country of export. This is of crucial importance to consumers as well as for the ethical standards and extraterritorial obligations of Europe.

Summary

PAGE 2, LINE 30-32: "If appropriate, the applicants should also make a proposal, for amending or complementing the conditions of the original authorisation, *inter alia* the conditions concerning future monitoring". We strongly recommend that this statement is removed.

It is not appropriate for applicants to suggest amendments to conditions or future monitoring – that is a task for regulators and politicians. Applicants, wider industry interests and the public can then comment on any proposals

The record of industry to date is that they have not responded to EFSA-suggested improvements to Post Market Environmental Monitoring and have chosen instead to develop their own approach. It is extremely likely that if they did make proposals they would be aimed at protecting their shareholders rather than the environment, human and animal health.

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No comments

Background as provided by EFSA

The draft guidance provides the background to the legal aspects of GM food and feed application renewals but fails to remind applicants that the regulations governing the marketing of GM food and feed were introduced to protect public health, animal health, biodiversity and the environment. We recommend that these basic facts are reiterated in the background.

Terms of reference as provided by EFSA Assessment
No comments

1. Introduction

PAGE 6, LINES 101, 102: We recommend that point d) should be deleted for the reasons given in our comments on the abstract and summary. It is not appropriate for applicants who stand to gain from weaker conditions and less onerous monitoring requirements to play such a role in regulating their own GMO.

2. Mandatory data requirements

The mandatory data required for the risk assessments of renewal applications for GM food and feed are the same as those required for an initial application. These have been challenged as being inadequate to establish the safety of GMOs and products based on GM crops on several grounds. The core criticism is that the approach adopted in the EU continues to be based on comparative risk assessment rather than a comprehensive risk assessment of the GMO. The last decade has produced huge progress in the understanding of genes, how they function and interact and how GM DNA and proteins can survive digestive systems:

Genes and enzymes are multifunctional. [ref: Hodges J, June 2009. *Foundations, Fallacies, and Assumptions of Science for Livestock in Development.* UN IAEA-FAO International Symposium on Sustainable Improvement of Animal Production and Health]

Genes are interdependent. [ref: Hodges, J 2009 as above]

Genes overlap in function. [ref: Hodges, J 2009 as above]

Information flows both to and from genes. [ref: Hodges, J 2009 as above]

Switches can modify gene expression. [ref: Hodges, J 2009 as above]

The genome is highly integrated, compact and efficient. [ref: Hodges, J 2009 as above]

“Junk DNA” is a myth – it is now known that DNA which does not code for protein is important at many levels such as gene expression and regulation, for cell division and biological time-keeping (eg ageing) or in crossing-over processes of chromosomal recombination. [ref: Hodges, J 2009 as above]

Epigenetics (altered gene expression – such as gene silencing – due to external influences including environmental stress, diet and lifestyle) plays an important role in heritable changes to gene expression. [ref: University of Chicago Press Journals, 20 May 2009. "Epigenetics: 100 reasons to change the way we think about genetics". Accessed at *Science Daily*, 25 September 2012]

Unexpected outcomes of GM events do occur. [ref: Prescott VE, Campbell PM, Moore A, Mattes J, Rothenberg ME, Foster PS, Higgins TJV and Hogan SP, 2005. "Transgenic expression of bean α-Amylase inhibitor in peas results in altered structure and immunogenicity". *Journal of Agricultural and Food Chemistry*. 53(23): 9023 – 9030]

GM DNA can survive the digestive system. [ref: Prescott VE, Campbell PM, Moore A, Mattes J, Rothenberg ME, Foster PS, Higgins TJV and Hogan SP, 2005. "Transgenic expression of bean α-Amylase inhibitor in peas results in altered structure and immunogenicity". *Journal of Agricultural and Food Chemistry*. 53(23): 9023 – 9030]

Continuing our evidence that the last decade has produced huge progress in the understanding of genes, how they function and interact and how GM DNA and proteins can survive digestive systems:

Micro RNAs can survive digestive systems, pass into the blood supply and potentially silence genes in the person or animal that consumed the food or feed. [ref: Zhang L, Hou D, Chen X, Li D, Zhu L, Zhang Y, Li J, Bian Z, Liang X, Cai X *et al.*, 2012. "Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA". *Cell Research* 22, 107-126]

There are compelling indications of horizontal gene transfer from GM food to gut organisms in humans. [ref: Zhang L, Hou D, Chen X, Li D, Zhu L, Zhang Y, Li J, Bian Z, Liang X, Cai X *et al.*, 2012. "Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA". *Cell Research* 22, 107-126]

The viral gene VI (with active domains overlapping with the Cauliflower Mosaic virus promoter sequence used in the majority of commercialised GM crops) was only identified as a potential health risk in 2012. It was first known to be in GM crops in 1980 but is not included in risk assessments by industry or regulators. [ref: Podevin N and du Jardin P, 2012. "Possible consequences of the overlap between the CaMV 35S promoter regions in plant transformation vectors used and the viral gene VI in transgenic plants". *GM Crops and Food* 3: 1-5]

To emphasise:
It is a combination of the novel gene and the impact of the gene insertion and transformation process on the rest of the genome that makes a GM crop different from a non-GM crop and hence: re-appraisal of GMOs should be based on a comprehensive risk assessment including compositional and nutritional analysis, rather than a comparative risk assessment. This should be a requirement both for first time applications and for renewal applications.

2.1. Identification of the transformation event(s)

We welcome the requirement for applicants to "confirm the identity of the event(s) for renewal authorisation by sequencing. In addition, the characterisation of the flanking sequences should provide updated sequence data for subsequent bioinformatic analyses".

We would strongly recommend that this should extend to genome-wide mutations which result from the original transformation process (including genetic sequence insertion processes and tissue culture) to ensure that they are identified, stable, have not given rise to and are not subject to, further mutations.

The draft guidance does not specify the techniques that should be employed to confirm the identity of event and flanking sequences. We recommend that these should be specified to ensure the best

possible data is available. A previous review found that Southern Blot analysis was insufficient to identify on-site mutations and proposed that PCR techniques and gene sequencing should also be used. [ref: Wilson A, Latham J and Steinbrecher R, (2006). "Transformation-induced Mutations in Transgenic Plants: Analysis and biosafety implications". *Biotechnology and Genetic Engineering Reviews*, 23: 209-237]. The same review also reported that flanking mutations could be larger than the 1kbp each side of the insert (the largest reported were 40 and 78kbp). We therefore recommend that the requirement to test for mutations in flanking sequences should be increased substantially, ideally to more than the largest recorded in literature and research documents. This should be a requirement both for first time applications and for renewal applications, with the latter providing both data sets.

PAGE 6, LINE 117: we suggest replacing "evolve" with "change", as 'evolve' has connotations of better or improved, both of which are not appropriate for this section and purpose.

PAGE 7, LINE 129: please insert "eg" or "such as" inside the bracket and add "translocations, inversions and amplifications" to the bracketed list. All forms of DNA changes (mutations) need to be carefully considered, not just those currently listed in the draft guidance.

PAGE 7, LINE 132/3: The language here is currently not sufficient and lacks clarity. It should be amended to ensure that statistically significant numbers of samples are taken from ALL the various varieties of GM plants (containing only the event, ie not stacked). It must also require geographical representation of the various varieties in order to derive datasets that can indicate whether changes have taken place within varieties (eg across geographical areas) and across varieties – and to which extent.

PAGE 7, LINE 134: Applicants should cover ALL the varieties that may be imported into the EU, but should justify the choice of geographical areas if not all are being covered.

2.2. Copy of the authorisation for placing the food/feed on the market
No comments.

2.3. Post-market monitoring and post-market environmental monitoring reports

Post Market Monitoring (PMM) and Post Market Environmental Monitoring (PMEM) by consent holders are unproven methods of ensuring that the assumptions in the original risk assessment were correct and that unexpected changes have been identified.

Significant changes such as weed and pest resistance may take many years to evolve. Glyphosate resistance in weed species was confirmed to occur in the USA 4 years after commercial growing started and in Argentina after 7 years [ref: Heap, I. The International Survey of Herbicide Resistant Weeds. Online. Internet. Thursday, December 11, 2014. Available at www.weedscience.org]. In India, Monsanto confirmed Bt-resistant pests in GM cotton in 2010, 8 years after the first commercial crop. [ref: Sharma, D, 2010. Bt Cotton Has Failed Admits Monsanto. India Today, 6th March 2010. Available at http://indiatoday.intoday.in/site/Story/86939/India/Bt+cotton+has+failed+admits+Monsanto.html]

EFSA itself has expressed concerns about methodology used in PMEM of MON810: "However, having already highlighted the poor sensitivity of the methodology followed by the applicant, the EFSA GMO Panel strongly reiterates its previous recommendations for the improvement of the methodology". [ref: Monsanto Europe, 2013.Annual monitoring report on the cultivation of

MON810 in 2012 Czech Republic, Portugal, Romania, Slovakia, and Spain. Available at http://ec.europa.eu/food/plant/gmo/reports_studies/docs/report_2012_mon_810/report_2012_mon_810_en.pdf]

A questionnaire sent to farmers growing GM crops may detect agronomic change over 10 years but is not designed to detect potentially significant indirect effects such as hybridisation with wild relatives, reduced activity of pollinators or other effects on non-target species in the surrounding area. Surveys of livestock farmers feeding MON810 maize to pigs or chickens have not been carried out as part of their PMEM programme.

Tenders for "Strategy Support for the Post Market Monitoring (PMM) of GM plants: Review of existing PMM strategies developed for the safety assessment of human and animal health (OC/EFSA/GMO/2013/03)" were invited in 2013. It is therefore unlikely that data has been evaluated so far and this re-enforces our view that PMM will provide limited information for re-approval applications at present. To be of value in the future PMM should be carried out independently and should be based on sample sizes which are capable of detecting significant changes in three years.

Thus far no specific attempts have been made to monitor farm animal health for effects of consuming MON810 maize. Monsanto has ignored EFSA's recommendations on improving general surveillance:

Monsanto acknowledges the fact that EFSA made several recommendations to improve the methodology on how to perform General Surveillance, i.e., in their general guidance document for post-market environmental monitoring (PMEM) of GM crops in August 2011 (EFSA, 20116) and two specific opinions on MON810 monitoring in the 2009 and 2010 growing seasons (EFSA, 20117; 20128). However, Monsanto chose to pursue its gained expertise on MON 810 monitoring and already established methodologies in order to report on the results for the 2012 growing season, and this decision has been taken for several reasons. Firstly, as said before, General Surveillance monitoring for MON810 cultivation is conducted by Monsanto on a voluntary basis. Currently, the consent allowing MON810 cultivation in the EU does not contain obligatory General Surveillance monitoring conditions (Commission Decision 98/294/EC). As long as no authorization decision has been reached on the MON810 renewal application (pending since 2007) containing General Surveillance monitoring as a condition of the consent, Monsanto elects to continue its current modus operandi. [ref: Monsanto Europe, 2013.Annual monitoring report on the cultivation of MON810 in 2012 Czech Republic, Portugal, Romania, Slovakia, and Spain. Available at http://ec.europa.eu/food/plant/gmo/reports_studies/docs/report_2012_mon_810/report_2012_mon_810_en.pdf

PAGE 7 LINE 160: add "and PMM" at end of sentence. Also add a new sentence requiring companies to list any feeding trials that have been carried out with the GM event since first approval, including published and non-published company (and company financed) trials as well as trials conducted by third parties.

This point is also relevant to be added at line 175 (as submitted under section 2.4.1)

2.4. New information

The Guidance should make it clear that the search for new information on a GMO must be as wide as possible.

Companies want their renewal applications to proceed without a hitch - so, without specific guidance, are likely to seek new information in the narrowest possible range of areas. The experience of renewal applications in the EU is limited but the evidence suggests that information searches are used to confirm the original risk assessment rather than review all research and highlight issues of concern that arise.

An example of Monsanto's desire to gloss over less favourable findings came in their 2012 PMEM for MON810. A paper by Gu et al. reported a potentially significant effect in salmon fed on Bt-maize:

"The data suggest that Cry1Ab protein or other antigens in Bt-maize have local immunogenic effects in salmon DI. No systemic immune responses could be detected, as indicated by haematology, differential leucocyte counts, plasma clinical chemistry, as well as absence of Cry1Ab-specific antibodies and Cry1Ab protein in plasma. The responses to Bt-maize observed in the present study differed from results from earlier studies in salmon and other animals fed the same event Bt-maize. Longer-term experiments and more in-depth studies on intestinal physiology and immune responses are needed to evaluate health implications".

[ref: Gu J, Krogdahl Å, Sissener NH, Kortner TM, Gelencser E, Hemre GI, Bakke AM.,2013. Effects of oral Bt-maize (MON810) exposure on growth and health parameters in normal and sensitised Atlantic salmon, Salmo salar L. British Journal of Nutrition 109 8, 1408-23. doi: 10.1017/S000711451200325X. Available at http://www.ncbi.nlm.nih.gov/pubmed/23182224]

It is clear that the authors of the study are calling for more long term research on the feeding of Bt maize, but Monsanto's PMEM report downplayed this, saying "that long-term observations and more in-depth studies on immune response and nutrient utilisation MAY be needed to confirm the results". (our emphasis)

In addition, new findings on the survival of GM DNA and proteins in the gut (Spisak et al in 2013, Alexander et al 2007 Agodi et al 2006, Mazza et al 2005) have not so far been covered by PMEM reports from Monsanto despite their relevance to the assumptions in the original risk assessment.

[ref 1: Spisák S, Solymosi N, Ittze´s P, Bodor A, Kondor D, et al. (2013). Complete Genes May Pass from Food to Human Blood. PLoS ONE 8(7): 69805.doi:10.1371/journal.pone.0069805. ref 2: Alexander, T.W., Reuter, T., Aulrich, K., Sharma, R., Okine, E.K., Dixon, W.T., and McAllister, T.A. (2007). A review of the detection and fate of novel plant molecules derived from biotechnology in livestock production., *Animal Feed Science and Technology,* 133(1-2), pp. 31-62. Ref 3: Agodi A., Barchitta M., Grillo A. and Sciacca S., 2006. Detection of genetically modified DNA sequences in milk from the Italian market, Int *J Hyg EnvironHealth,* vol. 209, pp. 81–88, ref 4: Mazza R., Soave M., Morlacchini M., Piva G. and Marocco A., 2005 "Assessing the transfer of genetically modified DNA from feed to animal tissues", *Transgenic Res.,* 14, 775–784]

Data from the monitoring of the agro-ecosystem, food and feed should also feature in renewal applications. To date MON810 PMEM reports have only looked at the development of pest resistance. There has been no attempt by Monsanto to monitor non-target species in areas where the crop is grown, despite a request from EFSA. This raises concern about the applicants' role in seeking new information, prompting the question: WOULD PUBLIC HEALTH AND ENVIRONMENTAL PROTECTION BE BETTER SERVED BY GIVING THIS TASK TO AN INDEPENDENT PUBLIC BODY? This approach, funded by an application fee, could be cost neutral for the applicants through reduced internal costs of monitoring and assessing new findings. Some findings would be relevant to more than one GMO and, if placed on an accessible public website, could assist farmers in deciding whether or not to grow GM crops. An independent monitoring body would also go some way to restoring public faith in the GMO regulatory system and would be able to intervene if new

information indicated that the GMO was unsafe. This could trigger the safeguard clause and possibly lead to the withdrawal of the approval. Industry could, of course, continue to generate their own information and evidence if they so wished.

2.4.1. Systematic search and evaluation of literature

The search for new information and data should be as wide as possible. It should not be confined to the GM trait(s) but should consider whole organisms and changes that may arise from the genetic modification, including indirect effects such as reductions in primary production in agro-ecosystems having implications for non-target organisms, toxic effects on non-target organisms, changes in GMO toxicity as a result of environmental interactions, and cumulative effects (for instance the effect of more than one GM herbicide tolerant crop being grown on individual farms, sub regions or regions).

The limited experience of PMM and PMEM (largely reports on MON810 maize) and of renewal applications suggests that consent holders are likely to limit the scope of their literature reviews and play down any findings or trends that may impact on re-approval. Therefore, it is essential that the guidance emphasises the importance of the widest possible literature search.

PAGE 8, LINE 169: Add: Applicants should also indicate where the research was carried out and whether it was funded by industry, including themselves. Furthermore, applicants should not attempt to reflect a consensus where indeed there is no scientific consensus.

PAGE 8, LINE 175: Add a new sentence requiring companies to list any feeding trials that have been carried out with the GM event since first approval, including both published and non-published company (and company financed) trials as well as trials conducted by third parties.

2.4.2. Updated bioinformatics

Updating of bioinformatics for re-approval of a GMO should be as comprehensives as possible and look at the whole GMO especially in the case of those with stacked GM traits.

Stacked GMOs should be treated like any other GMO as a novel organism with multiple traits rather than, as at present by EFSA, where safety is assumed on the basis of testing the individual traits in isolation. In addition, there should be a requirement to investigate possible interactions between the different GM traits present.

All types of analysis should be used to detect any changes in the genetic make-up (including epigenetics) of the GMO: changes in protein shape and structure; presence of novel chemicals and potential toxins; changes in nutritional content and quality; changes in anti-nutritional presence and amounts; bioassays on novel chemicals and proteins; and chemical and pesticide residues.

Bioinformatic information should also include the expression of the GM protein under different conditions likely to be experienced in the field (eg heat, cold, and disease stress as well as pesticide/herbicide stress) and in different part of the plant (eg pollen, roots, leaves and grain/seed).

Another requirement should be the listing of pesticide residue burdens (including herbicide residues) found in GM plants/crops and a comparison of altered transcriptomes and proteomes of high pesticide residue plants/crops as compared to unsprayed plants/crops.

PAGE 8, LINE 202: either replace “DNA” with “genetic material” or add “RNA”, as not all microbial genetic sequences are DNA.

PAGE 8, LINE 208-210: Previous sequence identity and identification data should also be included. There is likely to be a mix of old (original application) and new sequences (renewal application) present in crops/food/feed covered under the renewal application, as changes may have taken place in some multiplication lines, but not necessarily all.

2.5. Additional documents or studies performed by the applicant or third party

WHOLE SECTION

All research carried out on a GMO by applicants should be made available to EFSA and the public regardless of whether or not the results have been published or are incorporated in the final risk assessment. This should be made mandatory as it would assist the regulatory process. Greater transparency would also help restore public faith in the regulatory system.

There is a growing volume of research carried out by independent scientists into the safety of GMOs, despite difficulties in obtaining samples of GM crops/feed and their conventionally bred isogenic parent. In the past GMO research from independent scientists has often not been treated as equal to that carried out by or through the applicants to support their own application. The reasons for this are not entirely clear but may in part be due to independent researchers at times adopting different methodologies. When GMOs are being assessed for re-approval it is essential that peer-reviewed third party research is given at least equal weight to data from applicants (which is often not peer reviewed). Lack of consensus is a scientific reality and should be dealt with as such.

In the case of herbicide tolerant GM crops, monitoring should also cover, as mandatory element, the use and movement in the environment of the associated herbicide, whether under the Plant Protection Productions regulatory process (Regulation (EC) No 1107/2009), or via the renewals process. There is no denying that the approval of HT crops would greatly increase the environmental, farm animal and human exposure to a particular herbicide (the amounts detected would depend on farmer take up and how it was used). With Roundup Ready (RR) crop imports for feed, permitted and actual glyphosate residues in soya from North and South America are far higher than the EU and internationally agreed maximum residue levels (MRL) [ref: http://www.testbiotech.de/sites/default/files/TBT_Background_Glyphosate_Argentina_0.pdf]. This makes it essential that PMM and PMEM include routine monitoring of residues to ensure that they are below EU MRL. Animals fed on RR soya should also be monitored to ensure that they are healthy. As far as we know, monitoring of herbicide residues in animal feed or dairy products, meat and eggs does not currently take place in the EU. Other monitoring of food for herbicide residues by member states is patchy across the EU. It would therefore appear that animal products derived from animals fed GM HT soya are not currently monitored for herbicide residues.

Greenpeace estimates that, if the expansion of RR soya, maize and sugar beet crops witnessed in North and South America were repeated in the EU, glyphosate usage in the EU would rise by 800% and consequently residues in feed and food would also rise. [ref: http://www.greenpeace.org/international/Global/international/publications/agriculture/2012/438-Benbrook-Report-Summary.pdf] The limited monitoring of humans and farm animals for glyphosate residues which has been carried out to date has been done by independent scientists [ref: **Krüger M., Schledorn P, Schrödl W, Hoppe H-W, Lutz and Shehata AA, 2014.** Detection of Glyphosate Residues in Animals and Humans journal of Environmental Analytical Toxicology 4:2

http://dx.doi.org/10.4172/2161-0525.1000210] and NGOs [ref: Medical Laboratory Bremen,2013. Determination of Glyphosate residues in human urine samples from 18 European countries. Available at https://www.foeeurope.org/sites/default/files/glyphosate_studyresults_june12.pdf]. All samples have confirmed the presence of glyphosate in human and farm animal urine, emphasising the need for exposure to be monitored by official bodies in the EU on a regularly basis to feed into the GMO and pesticide approvals process.

PAGE 9, LINE 218
Please replace 'mention' with 'include' and add 'and withdrawals' after 'applications' to read in full: "The list should also include unsuccessful applications and withdrawals, providing the reasons…"

PAGE 9, LINE 226
We suggest a new section 2.6, which would require data on the change of agricultural practices due to the production of the GMO currently seeking renewal. This should include changes in pesticide regimes, such as increased levels and mixes of herbicides (eg 2,4-D) due to increased herbicide tolerance in weeds, in order to be able to test for the relevant residues and to enable customers/consumers to make informed choices.

3. Risk assessment

The risk assessment for re-approval of a GMO should be of the highest standard and should acknowledge where there are data gaps, inadequate data and scientific uncertainty.

The risk assessment should assess the whole GM organism and look for and assess unexpected genetic, chemical, compositional and metabolic changes based on a comprehensive analysis using all bioinformatics tools available.

It should also consider the potential negative impacts of its associated agricultural practices.

The risk assessment should be of the entire GMO on its own and its actual and potential negative impacts. It should not focus just on the intended GM traits as other (unintended) changes are equally relevant. Comparisons between the GMO and its isogenic parent cannot be deemed sufficient, as such comparison cannot provide a full picture. Please also see our comments under 2, mandatory data requirements).

Assessment should take into account GMOs which are already approved and released into the environment so that any cumulative and combinatorial effects on health and the environment can be assessed.

Cumulative and combinatorial effects are also important in the case of stacked GM crops which may contain several herbicide tolerance and insect resistance traits where the combination may alter the toxicity or allergenicity of the GMOs to humans, animals and non-target species. Data on such effects should be part of both a first application and a renewal application of a GM event.

Data gathered during PMEM and PMM by the applicants should be considered in the risk assessment, but not in isolation. Research and data from all sources should be assessed, in combination, including independent environmental and health monitoring data on (amongst other issues) herbicide residues along food chains, insect and weed resistance, soil health, gene transfer, horizontal gene transfer, crop health, indirect effects on the food chain in wild species, and farm animal health and welfare. Data should also be gathered and risk-assessed on gene expression and plant growth in different conditions (eg hot and dry, wet and humid.)

The direct and indirect environmental impact of the cultivation of GMOs in non-EU countries should be considered for crops licensed for import. It is unacceptable that the EU should have rigorous requirements for the environmental safety, human and animal health impacts of GMO cultivation in Europe but ignore this issue for imported crops. A particular concern is the intensive use of pesticides, including aerial spraying of herbicide mixes on HT crops and on so-called 'superweeds' that have developed as a consequence of the introduction of HT crops.

The risk of escapes and gene transfer from imported GM food and feed that also constitute seeds should also be part of the risk assessment.

Consideration should be given to the time required for indirect effects to become ecologically and/or socio-economically significant. This is particularly important when the GMO is one of many similar events being grown.

Feed and food safety testing are a controversial area of research. Current risk assessments (and hence assessment of re-approvals) rely entirely on short term laboratory feeding trials which are largely designed to detect acute toxicity and have a limited range of parameters and data required. Feeding trials limited to 90 days cannot assess long term toxicity (including low level chronic toxicity), reproductive health impacts, chronic and acute lifetime effects and intergenerational effects. To fully assess the safety of GM feed and food, feeding studies should span at least two years.

4. Monitoring plan and proposal for improving the conditions of the original authorisation

PAGE 9, LINE 238: Add "increased" to read: "If increased, new or additional risks ….".

Studying the effects of the release of GM food and crops on health and the environment is a complex task. In the future crops on farms could be genetically engineered with a wide range of different traits, such as herbicide tolerance, insect resistance, disease resistance, abiotic stress tolerance and changed nutritional value (if such GM traits become technically possible, are proven safe and are acceptable to the public).

Sifting through field and laboratory generated data to pick up on unexpected direct and indirect impacts, possible synergistic effects of genes in stacked GM crops, or arising from hybrid varieties or hybridisation with wild crop relatives, will require a sophisticated approach both to gathering and analysing data.

PMEM has only been required for two crops in the EU to date (MON810 maize and BASF's Amflora potato (now withdrawn)). EFSA's suggestion to improve the general surveillance of GMOs in their scientific appraisals of MON810 monitoring reports have so far been rejected by Monsanto (see our comments on 2.3).

It would be illogical to imagine that applicants for re-approval of a GMO would make suggestions for making consent conditions more onerous for themselves and it is not a role that they should be asked to fulfil. Furthermore it is unlikely that applicants will be willing to undertake the sort of field monitoring that may be required to detect long-term indirect or synergistic effects between different GM traits. It is worth remembering that during independent monitoring of GM oilseed rape during the UK's government sponsored Farm Scale Evaluation from 1999-2003, a hybrid seed of GM herbicide tolerant oilseed rape and the arable weed Charlock (*Sinapsis arvensis*) was found. [ref:

Daneils R. et al., 2005. The potential for dispersal of herbicide tolerance genes from genetically-modified, herbicide-tolerant oilseed rape crops to wild relatives. Contract reference EPG 1/5/151] Previously this cross was thought to be impossible under field conditions. The implications of arable weeds picking up herbicide tolerance genes in addition to the natural evolution of herbicide resistance, which is already well documented, are significant for farmers (higher costs and more difficult weed control), public health (increased risk of herbicide exposure via air, food and water) and the environment (increased risk of herbicide pollution and damage).

Our proposal is therefore for PMEM and PMM to be taken out of the hands of the applicants and into a transparent, publicly accountable independent body specifically set up to carry out this role. That body would also be required to liaise with other national agencies involved in environmental monitoring and surveillance to avoid unnecessary duplication of activities and facilitate collaboration on methodologies and field practice. Applicants for new and re-approvals could be charged an appropriate application and licensing fee to cover the costs of the independent body. They would then be spared the costs of having to do it themselves.

Documentation provided to EFSA
No comments

References
No comments.