

Briefing note on the EU's GMO reform debate

August 2008

The French Presidency has set up an Ad Hoc Working Group on GMOs. This briefing note outlines Greenpeace and Friends of the Earth's concerns in the areas that the Group will be focusing on, along with our demands for the way forward.

1. The environmental risk assessment process has to be reformed

The current EU authorisation process of GMOs is affected by a fundamental problem. The opinions (all positive to date) provided by a single EU body, the European Food Safety Authority, are constantly translated into decisions, despite their lack of assessment on the environmental, health, societal and economic impacts of GMOs.

Member state and other experts have consistently highlighted fundamental flaws in EFSA's opinions since the Authority was set up in 2002. Assessments of the long-term health and environmental impacts of GMOs and their effects on non-target organisms are not being carried out despite these being required under EU legislation¹ and the assessments are based on the applicant company's own data, which is often incomplete and of poor quality.²

Furthermore, by signing its two-year mandate to improve its knowledge on the long-term environmental risk assessment of GM plants,³ EFSA has publicly acknowledged its inability to fulfil legal requirements, namely to assess long-term environmental impacts.

The way forward:

- a) Independently conducted long-term environmental impact assessments in all the EU biogeographical regions must be carried out to prove that the GM crop does not cause adverse effects on the receiving environment. The results should be presented as part of the application dossier.
- b) Until EFSA has completed its mandate to improve its knowledge on the long-term environmental risk assessment of GM plants, it cannot be issuing any opinions on crops for cultivation in the EU.

2. Pesticide-producing GMOs: too much uncertainty to be authorised

In the past two years, new studies have demonstrated the inability of the EU risk assessment procedure to evaluate the risks of pesticide-producing GMOs (i.e. Bt maize). These studies show that the effects of Bt maize varieties are far from predictable and their potential for harm is even greater than previously thought, for example:

- The cultivation of Bt maize has resulted in one pest being replaced by another;⁴
- The Bt toxin from Bt maize may affect headwater stream ecosystems;^{5, 6}

¹ Directive 2001/18/EC, Article 14(4).

² European Communities – Measures affecting the approval and marketing of biotech products (DS291, DS292, DS293). Comments by the European Communities on the Scientific and Technical Advice to the WTO Panel, paras 762 and 763

³ See: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionDetailsRO.jsf>

⁴ Catangui M.A. & Berg R.K. 2006. Western bean cutworm, *Striacosta albicosta* (Smith) (Lepidoptera : Noctuidae), as a potential pest of transgenic Cry1Ab *Bacillus thuringiensis* corn hybrids in South Dakota *Environmental Entomology* 35 1439-1452.

⁵ Rosi-Marshall, E.J., Tank, J.L., Royer, T.V., Whiles, M.R., Evans-White, M., Chambers, C., Griffiths, N.A., Pokelsek, J. & Stephen, M.L. 2007. Toxins in transgenic crop byproducts may affect headwater stream ecosystems. *Proceedings National Academy of*

- The level of toxin produced by MON810 maize varies;⁷
- Bt toxin affects the behaviour of monarch butterfly larvae;⁸
- Target insects develop resistance to the pesticides produced by these GM crops;⁹
- The toxin actually produced by MON810 maize is likely to be different from the Bt toxin used to test the crop's environmental safety, invalidating most MON810 environmental 'safety' tests.¹⁰

In February, 37 scientists from 11 countries wrote an open letter to Environment Commissioner Stavros Dimas supporting his proposal to reject the authorisation for cultivation of two GM Bt maize varieties (1507 and Bt11). They suggested in their letter that no new Bt crops should be authorised for cultivation until the controversy on risk assessment is resolved.¹¹

The way forward:

- c) In light of all of the negative environmental effects observed on Bt crops, and of the outstanding scientific uncertainties, the precautionary principle must be invoked to prevent the cultivation of Bt crops in the EU.
- d) Assessments of the impacts on non-target organisms and on long-term negative effects of Bt crops on health and the environment are legal requirements that must be respected.

3. Herbicide-tolerant GMOs: their detrimental impacts are neglected

The introduction of GM herbicide-tolerant crops - tolerant to herbicides such as glyphosate (also known as Roundup) - have caused an increase in weed resistance in the US, Argentina and Brazil.

- In the US the widespread adoption of Roundup Ready crops combined with the emergence of glyphosate-resistant weeds has driven a more than 15-fold increase in the use of glyphosate on major field crops from 1994-2005.¹²
- In Argentina, new glyphosate-resistant weeds are replacing the usual weeds found in the fields, as a result of the cultivation of GM herbicide tolerant soya.¹³ Farmers are being advised to use other, more notorious herbicides in addition to increasing volumes of glyphosate to control glyphosate resistant weeds.¹⁴
- In Brazil, glyphosate use grew 79.6% from 2000 to 2005, mainly due to the expansion of RoundUp Ready soybeans.¹⁵

Sciences of the USA 41: 16204–16208.

⁶ Bøhn, T., Primicerio, R., Hessen, D.O. & Traavik, T. 2008. Reduced fitness of *Daphnia magna* fed a Bt-transgenic maize variety. Archives of Environmental Contamination and Toxicology DOI 10.1007/s00244-008-9150-5

⁷ Nguyen, H. T. & J. A. Jehle 2007. Quantitative analysis of the seasonal and tissue-specific expression of Cry1Ab in transgenic maize Mon810. Journal of Plant Diseases and Protection 114: 820-87.

⁸ Prasifka, P.L., Hellmich, R.L., Prasifka, J.R. & Lewis, L.C. 2007. Effects of Cry1Ab-expressing corn anthers on the movement of monarch butterfly larvae. Environmental Entomology 36:228-33

⁹ Tabashnik, B.E., Gassmann, A.J., Crowder, W. & C. arrière, Y. 2008. Insect resistance to Bt crops: evidence versus theory. Nature Biotechnology 26: 199-202.

¹⁰ Rosati, A., Bogani, P., Santarlasci, A. Buiatti, M. 2008. Characterisation of 3' transgene insertion site and derived mRNAs in MON810 YieldGard maize. Plant Molecular Biology DOI 10.1007/s11103-008-9315-7.

¹¹ The letter can be found on the internet at: <http://www.vdw-ev.de/Scientists%20letter%20to%20Dimas.pdf>

¹² Agricultural Chemical Usage: Field crops summary, USDA National Agricultural Statistics Service

¹³ Vitta, J.I., Tiesca, D. & Puricelli, E. 2004. Widespread use of glyphosate tolerant soybean and weed community richness in Argentina. Agriculture, Ecosystems and Environment, 103, 621-624.

¹⁴ See, e.g. http://farmindustrynews.com/mag/farming_saving_glyphosate/index.html

¹⁵ Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis (IBAMA) Calor Economico, April 2007; IDEC

The way forward:

- e) Herbicide tolerant GM crops, and the herbicide they are tolerant to, must be subject to a uniform assessment which considers the environmental and agronomic impacts of an increased use of the same herbicide in European fields.
- f) A specific body holding the necessary scientific expertise to assess these impacts must be charged with such a task.
- g) Until a thorough assessment is carried out, the negative effects of herbicide tolerant GM crops can only be prevented by not introducing them into European agriculture.

4. Criteria to assess the negative socio-economic impacts of GMOs need to be included in the risk assessment

EU GMO legislation requires other legitimate factors (other than health and environmental effects) to be taken into account in the authorisation process.¹⁶

In the 12 years since GM crops entered the market, conventional and organic crops have been repeatedly contaminated with GMOs – and farmers and the food industry have paid the consequent economic and social price. The small acreage of Bt maize planted in Spain has already caused significant social problems by creating tensions between neighbouring farmers.¹⁷

Industrial-scale farming, promoted by GM crops, develops at the expense of small farms growing diverse produce for local needs and is problematic to the organic industry. The area planted with organic maize was reduced by 75% in Aragon (Spain), where most of the GM Bt maize is concentrated.¹⁷

Four companies – Monsanto, DuPont-Pioneer, Syngenta and Bayer – sell 41% of all commercial seeds globally. Monsanto has a virtual monopoly: its GM traits are found in 86% of biotech crops globally.¹⁸ Rising prices due to the consolidation of the market, combined with reduced variety, is decreasing seed choices available to farmers.

Patented GM seeds not only increase the price of production but also threaten to undermine the age-old tradition of farmers saving and sharing seed – a practice that have been the basis of food security for millennia. In the US, farmers are routinely investigated and sued by Monsanto for saving seeds and for having been unwittingly contaminated with Monsanto's patented traits.¹⁹

The way forward:

- h) The cultivation of GM crops has led to several adverse socio-economic effects, thus it is important to consider these factors in the assessment.
- i) Changes in agricultural practices, impacts on social networks, loss of traditional farming knowledge, costs to prevent contamination are “legitimate factors” that must be considered during the authorisation of GMOs.
- j) A body with the necessary expertise (i.e. independent from EFSA) should be involved in assessing socio-economic impacts of GM crops.
- k) Legally binding strict liability legislation should be put in place to cover cases of GMO contamination and other negative effects, to ensure that the polluter, not the farmer, pays.

¹⁶ Regulation 178/2002 (the founding regulation of EFSA), recital 19.

¹⁷ Binimelis, R. 2008. Coexistence of plants and coexistence of farmers: is an individual choice possible? Journal of Agricultural and Environmental Ethics doi 10.1007/s10806-008-9099-4

¹⁸ ETC group, 'The World's top 10 seed companies', http://www.etcgroup.org/en/materials/publications.html?pub_id=615

¹⁹ Centre for Food Safety, updated 2007: Monsanto vs US Farmers <http://www.centerforfoodsafety.org/Monsantovsusfarmersreport.cfm>

5. Ecological expertise must receive equal weight

EFSA's scientific expertise is clearly not sufficient for it to fulfil its role. Only two out of 21 scientists on the GMO panel have expertise in environmental sciences or ecology, while the others are specialists in biotechnology. The lack of cross-disciplinary expertise has already led to serious mistakes being made in EFSA opinions, for example

- Monsanto's data analysis of GM maize variety MON863 was seriously flawed, as proved by independent scientific analysis,²⁰ but EFSA failed to recognise this.
- EFSA, in its classification of the antibiotic resistant marker gene (ARMG) inserted in the BASF potato, contradicted the findings of the World Health Organisation. EFSA's classification was also rejected by the European Medicines Agency (EMA).²¹

EFSA, as an Agency entrusted with risk assessment, has a tradition of checking food not seeds, for which environmental effects are much more crucial. An appropriate environmental risk assessment could only be carried out by an institution with strong environmental and ecological expertise. The European Environmental Agency should be considered as an appropriate expert Agency.

The way forward:

- I) The European Environmental Agency (EEA) needs to participate in GMO risk assessment procedures concerning cultivation applications in order to provide the necessary environmental expertise.

6. Ensure seeds purity

Establishing thresholds for GMO contamination of seeds would lead to an uncontrollable and untraceable spread of GMOs, as seeds grow into reproducing plants which can multiply and outcross to wild relatives and persist in the environment.

Allowing seed contamination would undermine several EU provisions on GMOs. Directive 2001/18, as well as the labelling and traceability Regulations 1829 and 1830/2003, require that GMOs released into the environment are monitored, labelled and traceable, to withdraw them from the market if needed. However, it would be practically impossible to withdraw from the market or fields thousands, or millions, of individual GM plants resulting from contaminated seeds.

Allowing even a minimal level of contamination of conventional seed stocks would make GMO-free agriculture impossible and would condemn conventional and organic producers. Allowing seed producers to sell contaminated seeds (at 0.3%, 0.5% or 0.7% levels) without any label, will unjustly make it even more difficult for all subsequent economic operators to keep contamination under the labelling threshold of 0.9%. Under EU law routine GMO presence in seeds cannot be regarded as "adventitious", therefore subsequent GM presence in products, even below 0.9%, will have to be labelled.

The social and economic costs that such a proposal implies are not justifiable even from a strict economic point of view. Indeed, keeping one ton of seeds GMO-free will under all circumstances be much cheaper than testing the hundred tons of crops that these seeds will produce.

²⁰ Séralini, G-E, Cellier, D. & Spiroux de Vendomois, J. 2007. New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity. Archives of Environmental Contamination and Toxicology DOI: 10.1007/s00244-006-0149-5.
²¹ Lasok, K.P.E. QC (2007) Opinion in the matter of a proposed Commission Decision concerning the placing on the market, in accordance with Directive 2001/18, of a genetically modified potato product <http://www.greenpeace.org/raw/content/eu-unit/press-centre/policy-papers-briefings/legal-briefing-on-basf-gm-potato.pdf>

The way forward:

- m) Seed purity must be ensured below the limit of detection. No higher threshold should be established..

7. Establish GMO-free zones in order to protect conventional crops

Directive 2001/18 demands an environmental risk assessment that covers all types of environment and all geographical zones in which the GMO shall be released.^{22, 23, 24} The term 'biogeographical region' indicates a set of habitat types and ecosystems with specific individual features. These ecosystems have been recognised by the EU through their inclusion in the Habitats Directive (92/43/EEC).²⁵

The scientific and legal acknowledgement of the biogeographical regions in the EU requires, therefore, a specific environmental risk assessment to be carried out assessing all the specific conditions prevailing in the 27 Member States. However, practice shows that this is far from exhaustive. The lack of, or an insufficient, risk assessment considering the EU's nine biogeographical regions is not only in breach of Directive 2001/18/EC but also violates the Habitats and the Birds Directive (79/409/EEC),²⁶ which oblige Member States to maintain and safeguard specific animal and plants species as well as habitats protected under EU law.

By only applying the Commission Recommendation on Co-existence, member states are displacing the fundamental conflict of GM and non-GM coexistence concerns to the level of individual farmers, and thus escape their responsibility. In order to alleviate the burden on local conflict resolution, land-use planning should be employed to allow an appropriate separation between GMO and non-GMO agriculture.

The way forward:

- n) Each authorisation must specify what the GMO can be used for and in which biogeographical zones it may be released.
- o) Agricultural zones free of GMOs should be established in order to prevent contaminating traditional crops with GMOs.
- p) Crops submitted for authorisation and re-authorisation must undergo specific environmental risk assessments in all of the biogeographic regions of the EU.

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²² See Recital (19) to Directive 2001/18.

²³ See Article 4(3) Directive 2001/18.

²⁴ See Annex II, Point B Directive 2001/18.

²⁵ Council Directive 92/43/EEC on the conservation of natural habitats and of wild flora and fauna.

²⁶ Council Directive 97/409/EEC on the conservation of wild birds