

## Fact sheets on genetically modified organisms

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## Flaws in the EU authorisation process for GMOs

There exists a fundamental problem in the process by which GMOs are assessed for safety and authorisation in Europe.

Scientific opinions provided by a single organisation, the European Food Safety Authority (EFSA), are translated into decisions with no broader consideration of societal or economic arguments for and against the introduction of GMO crops and products into Europe.

This situation contravenes EU legal requirements for a broad consideration of a GM product's risks and impacts.

### Risk assessment versus risk management

EFSA's founding regulation articulates the distinction between risk management and risk assessment:

Risk assessment is EFSA's task. It coordinates scientific committees, which provide advice to decision-makers<sup>1</sup>.

Risk management, in contrast, is the job of the European Commission. To make a decision, it should consult experts, including EFSA, but also national authorities, the European Group on Ethics in Science and New Technologies, and other stakeholders.

'Risk management' "means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options"<sup>2</sup>.

At present, EFSA's decisions form the sole basis for EU authorisations of GMOs (all positive decisions to date).

### Socio-economic factors must be considered

The European Commission is obliged, under EU law, to consider other available scientific evidence, socio-economic implications and scientific

The Commission asked EFSA (April 2006, IP/06/498) "to provide more detailed justification, in its opinions on individual applications, for not accepting scientific objections raised by the national competent authorities" and "to address more explicitly potential long-term effects and bio-diversity issues in their risk assessments for the placing on the market of GMOs".

Over 20 member states criticised EFSA for failing to conduct long-term evaluations of GMOs and for ignoring member states' comments and concerns (Environment Council, 9 March 2006).

uncertainty. Armed with this broader set of data, it must take a decision.

As EC Regulation 178/2002 states: "It is recognised that scientific risk assessment alone cannot, in some cases provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls"<sup>3</sup>.

There is no evidence to suggest that the European Commission currently takes these 'other factors' into account.

### Duty to follow predominant position

The European Commission pledged (in 1999) to "act in such a way as to avoid going against any predominant position which might emerge within the Council against the appropriateness of an

implementing measure"<sup>4</sup>.

In fact, the Council has consistently questioned the safety and usefulness of the GM products submitted for authorisation and has voted against the Commission's positive proposals. Never have member states given majority backing to a GMO for marketing or cultivation in Europe.

By approving every GMO application to date, the Commission has consistently disregarded its pledge to respect a 'predominant position' within the Council.

### European Food Safety Authority (EFSA) risk assessments

EFSA must also bear its share of the blame, as it, too, has violated obligations.

- By not requesting that GMO producers submit any data on the long-term effects of GM products for which they seek EU authorisation, EFSA has failed to identify and evaluate cumulative long-term effects of GMOs as

Figure 1: Authorisation process according to EU law

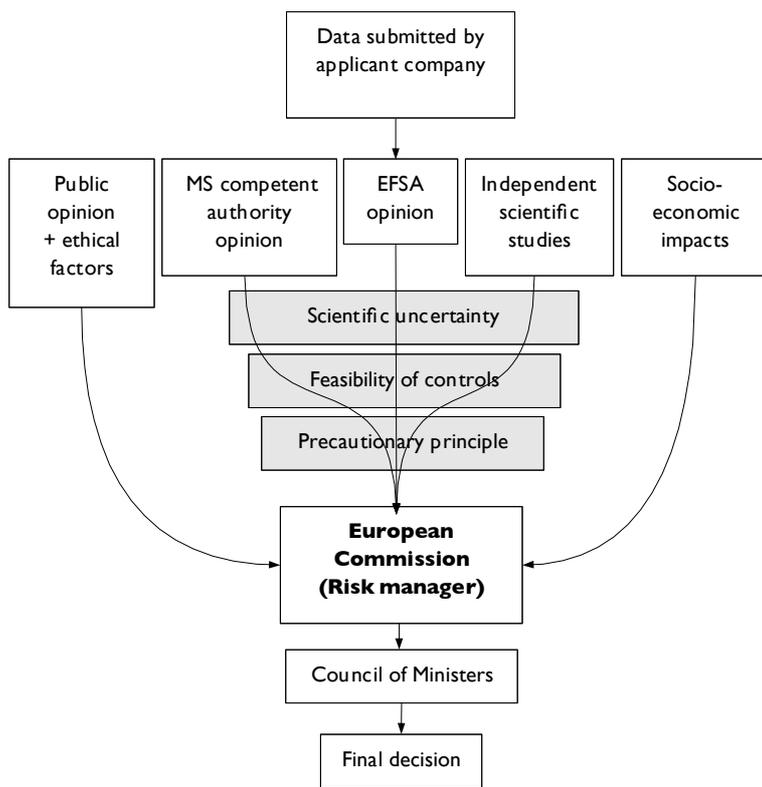
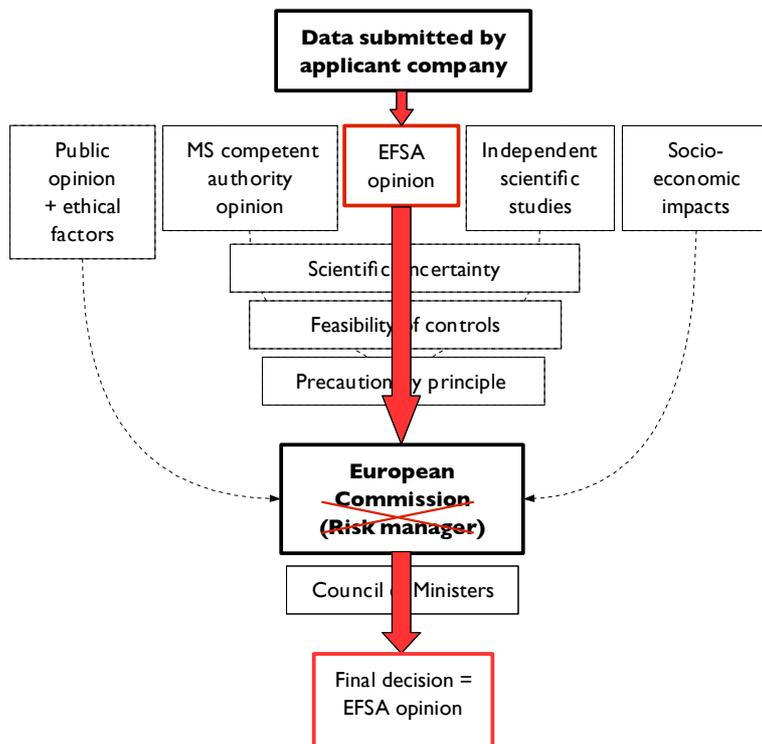


Figure 2: Current process



required under Directive 2001/18 and Regulation 178/2002<sup>5</sup>;

- Despite a legal requirement to consider diverging scientific opinions [Reg. 178/2002]<sup>6</sup>, there is no evidence that the EFSA has given due consideration to differences between the scientific opinions of member states' competent authorities and those of its own GMO panel .
- EFSA is supposed to identify areas of scientific uncertainty [Comm Decision 2002/623; Reg. 178/2002]<sup>7</sup> but, in practice, EFSA does not do so. Failing to acknowledge that uncertainty exists compromises the ability of risk managers (Commission and member states) to make informed decisions in the public interest.

Proper assessment of GMOs would include a study of direct, indirect, cumulative and long-term effects of GMOs on the environment and on health, taking into account various stress conditions and different regional environments.

## Conclusion

EFSA was not set up to rubber-stamp GMO applications from agro-chemical firms. EFSA must respect EU law and strictly follow the prescribed procedures.

The Commission must perform its role as risk manager and consider other available scientific evidence, socio-economic implications and scientific uncertainty.

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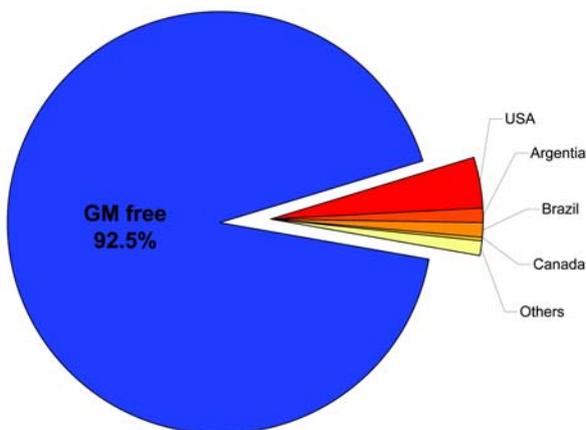
- 1 EFSA Executive Director Catherine Geslain-Lanéelle says the role of EFSA is to "advise European Union risk managers on the safety of GMOs. EFSA's experts make an independent scientific assessment of GMO applications. It is then up to Member States and the European Commission to decide whether or not to authorise a specific GMO". [http://www.efsa.europa.eu/EFSA/News\\_PR/pr\\_gmo\\_en,0.pdf](http://www.efsa.europa.eu/EFSA/News_PR/pr_gmo_en,0.pdf)
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- 3 Regulation 178/2002, Recital 19
- 4 European Commission Declarations on Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (1999/C 203/01).
- 5 See Directive 2001/18/EC on the deliberate release of GMOs, Annex II as well as Regulation 178/2002 establishing the European Food Safety Authority, Article 14(4).
- 6 Regulation 178/2002, Article 30(4) "Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public"
- 7 Regulation 178/2002, Article 7(1) "In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment".

## Facts and figures about genetically modified organisms

Every year, an organisation funded by the genetic engineering industry called the International Service for the Acquisition of Agri-biotech Applications (ISAAA) publishes new figures and highlights the increase in the acreage of land planted with genetically modified organisms (GMOs) across the world<sup>1</sup>.

These are the facts that the ISAAA does not put in its press release:

- 92% of arable land around the world is GMO free;
- Only four countries grow almost 90% of the total GM crops;
- 176 out of the 192 countries grow no GMOs at all;
- In over 10 years on the market, only four GM crops are grown in significant quantity – soya, maize, cotton and oil-seed rape (canola). These four crops represent 99% of GMOs sold;
- Virtually 100% of world acreage planted with commercial GM crops have one or both of just two traits: herbicide-tolerance and insect-resistance.



The four countries that grow 90% of GMOs worldwide are the US (53%), Argentina (18%), Brazil (11.5%) and Canada (6.1%).

Almost all GM crops currently released belong to four companies: Monsanto, Dupont, Syngenta and Bayer.

Monsanto sells more than 90% of all GM seeds worldwide. In recent years it has stopped selling or developing GM wheat, tomatoes, potatoes and bananas. It has given up trying to sell GMOs direct to the public, and now focuses on commodity crops which go straight from farmer to industrial processor.

A decade after GM maize was first marketed, six of the world's top 10 maize producing countries are 100% GM-free. Even in the US, GM maize represents less than half of all maize grown.

Worldwide, just 7.5% of farmland is planted with GMOs. The world map in the ISAAA report<sup>1</sup> shows countries where up to 50,000 hectares are planted with GMOs, failing to indicate that most of these countries plant only a few hundred hectares. Claims that Europe is alone in not planting GM crops are patently inaccurate.

In Europe, ISAAA stated a 77% increase in cultivation of GMOs in 2007, still only 0.119 % of agricultural land was planted with such crops. (This is how a very small increase in acreage can be made to look like enormous progress.) For comparison, in 2006 organic farmland represented 4% of EU agricultural land, covering an area larger than 6.8 million hectares managed by over 170,000 farms.

With these poor results, is it any surprise that US government representatives and agro-chemical lobbyists are putting such pressure on Europe and developing countries to accept GMOs?

### The power of public relations over fact

In its heavily promoted reports, the ISAAA assumes that the entire population of any country where GMOs are grown benefits from GM crops. It calculates, for example, that 80 million people in Germany - the total population - benefit from GMO crops, even though the 43km<sup>2</sup> of German soil planted with GMOs could barely support 8,000 people, let alone 80 million.

Claims that GM crops increase yields are similarly exaggerated. The GM crops currently commercialised are either tolerant to herbicides or insect resistant. Herbicide-tolerant crops do not increase yields.

Insect-resistant GM crops may increase yields in years of high infestation by the target pest, but this leads pests to develop resistance in the medium and longer term. Studies in Europe found that yield depend on the crop variety<sup>2</sup> rather than on the genetic modification applied. Studies have also found lower yields from GM insect-resistant maize compared to conventional non-GM maize.

Neither does planting GM crops reduce the use of chemical pesticides on farmland, despite what agrobiotechnological companies claim. In fact, from 1996 to 2004 parallel to increasing cultivation of GM crops in the US there was an observed 55,000 kg increase in pesticide use, a 4.1% rise<sup>3</sup>.

The target pest insects will inevitably develop resistance to the pesticides produced by GM crops<sup>4</sup>. This will oblige farmers to apply both greater quantities and additional varieties of insecticide in the coming years. The main beneficiaries then become the companies that make pesticides, which are often the same companies that make GMOs.

Any perceived benefits of GM crops – such as increased yields in occasional years and reduced insecticide usage – are thus short-lived.

Meanwhile, various scientific studies have concluded serious and valid concerns on the effects of these crops on 'non-target' organisms such as butterflies and predators of the target pests.

Recently, the International Assessment of Agricultural Science and Technology for Development<sup>5</sup> brought together 400 scientists, UN agencies, governments, non-governmental organisations, industry and farmer associations across the globe for a four-year scientific project. This is the equivalent for agriculture as is the IPCC report for climate change. The Synthesis Report, endorsed by 60 governments, concludes that genetically modified crops are not a solution for poverty, hunger or climate change.

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## Environmental and health impacts of GMOs: the evidence

### Effects on biodiversity

The environmental effects of genetically engineered crops designed to resist insect pests and herbicides are well documented. They are as follows.

**Insect-resistant crops** kill specific pests known to threaten the crop. In addition to their intended deadly effects, they are also:

- Toxic to 'non-target' organisms, such as butterflies. Long-term exposure to pollen from GM maize that expresses the *Bacillus thuringiensis* (Bt) toxin has been found to cause adverse effects on the behaviour<sup>1</sup> and survival<sup>2</sup> of the monarch butterfly, the best-known of all North American butterflies. Effects on European butterflies are virtually unknown, as few studies have been conducted. Those few do, however, suggest cause for concern that European butterflies would suffer as a result of insect-resistant GM crop being planted<sup>3,4,5,6</sup>.
- Toxic to other, beneficial insects. Genetically engineered Bt crops adversely affect<sup>7</sup> insects that are important in the natural control of maize pests, such as green lacewings.<sup>8,9,10,11</sup> In the EU (as elsewhere), environmental risk assessment for Bt crops considers direct acute toxicity alone, and not effects on organisms higher up the food chain. These effects can be important. The toxic effects of Bt crops on lacewings were via the prey that they ate. The 'single-tier' risk assessment approach has been widely criticised, with scientists suggesting that the effects of Bt crops need to be studied at multiple levels of the food web<sup>12,13,14,15</sup>.
- A threat to soil ecosystems. Many Bt crops secrete the toxin from the root into the soil<sup>16</sup>. Residues left in the field contain the active Bt toxin<sup>17,18,19</sup>. The long-term, cumulative effects of growing Bt maize have not been considered in a European context, even though this is required under EU law (Directive 2001/18)<sup>20</sup>.

GM maize MON810 is intended to prevent the need for three applications of insecticide. Yet this and other Bt maize varieties continuously release a toxin into the environment in quantities 3-5,000 times higher than sprays used for non-GM farming.

In addition to the above, risk assessments to date have failed to foresee at least two other impacts of Bt maize:

- Agricultural wastes from Bt maize have been identified entering water courses, where the Bt toxin might be toxic to certain insects<sup>21</sup>. This demonstrates the complexity of interactions in the natural environment and underlines the shortcomings of the risk assessment.
- Bt maize is more susceptible to a plant lice (aphid) than conventional maize, caused by changes in sap chemistry. These changes have not been described in a single application to market Bt maize but have important ecological implications. This demonstrates that plant-insect interactions are too complex to be assessed by the risk assessment.

**Herbicide tolerant (HT) crops** are associated with:

- Toxic effects of herbicides on ecosystems. Roundup, the herbicide sold by Monsanto in conjunction with its Roundup Ready GM crops, has been shown to be a potential endocrine disrupter, i.e., could interfere with hormones<sup>22</sup>. It is also toxic to frog larvae (tadpoles)<sup>23</sup>.
- Increased weed tolerance to herbicide. Evolution of weed resistance to Roundup is now a serious problem in the US and other places where Roundup Ready crops are grown on a large scale<sup>24,25,26,27</sup>. Increasing amounts of herbicide have to be used to control these weeds<sup>28</sup>, or else additional herbicides have to be used to supplement Roundup<sup>29</sup>.
- Loss of weeds and other biodiversity. A UK government study found there were 24 % fewer butterflies in the margins of GM oil-seed rape (canola) fields, because there were fewer weed flowers (and hence nectar) for them to feed on<sup>30</sup>. In addition, there were fewer seeds for birds from oil-seed rape and sugar beet<sup>31,32,33</sup>. HT maize only compared favourably (in terms of impacts on biodiversity) to maize treated with the herbicide atrazine, which is now banned in the EU.
- Reduction in soil bacteria. The use of herbicides on GM soy leads to reduced amounts of beneficial nitrogen-fixing bacteria<sup>34,35</sup>.

## Effects on health

Independent studies on the wholesomeness of GM crops for either animals or humans are severely lacking from scientific literature<sup>36, 37, 38, 39</sup>

Almost all GMOs commercialised in the world either produce or tolerate pesticides. Yet while pesticides are tested over two-year periods prior to approval in Europe, the longest safety tests for GMOs are 90 days, including pesticide-producing GM plants.

We simply do not know if GM crops are safe for animal or human consumption, because long-term studies have seldom been performed. This is reflected by the ongoing controversy surrounding their safety assessment. The dispute over the pesticide-producing Bt maize MON863, for example, arose from concerns expressed by independent scientists<sup>40</sup> over observed differences in animal feed trials. Rather than admitting uncertainty concerning the food safety of MON863 and carrying out further research, EFSA<sup>41</sup> and the biotechnology<sup>42</sup> industry have used their efforts to try to refute the significance of these findings.

It is ungrounded and misleading to argue that GMOs must be harmless to health on the grounds that people living in the US have been consuming them for 10 years and no visible damage has been observed. There has not been a study on this specific matter.

What is not in doubt is that GM crops have the potential to cause allergenic reactions, more so than conventional breeding<sup>43, 44</sup>. During a long-term field trial in Australia, for example, GM peas were found to cause allergenic reactions in mice<sup>45</sup>. Eating the GM peas also made the mice more sensitive to other food allergies.

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## The social and economic impacts of GMOs

Companies that develop and sell genetically engineered seeds say that everyone – from rich to poor; farmer, consumer or industrialist – benefits from their crops.

A brief look beyond the hype and promotional brochures would tell a different story.

**In the 11 years since GM crops entered the market, conventional and organic crops have been repeatedly contaminated with GMOs – and farmers have paid the price.**

Contaminated crops demand a lower price than conventional or organic crops. In Brazil in 2007, conventional soya was contaminated with up to 9% GMOs<sup>1</sup>, but there was no compensation for the farmers affected. Practically no country in the world has a law ensuring that GMO producers or growers are held liable for genetic contamination.

**New GM crops do not reduce farmers' reliance on pesticides and herbicides**

Ecological systems cannot be fooled: if a pest or weed species is removed from the food web, another moves in to replace it. In India in 2007 the cotton harvest was either not effective against Indian cotton pests or devastated by a 'secondary' pest that was not deterred by the Bt toxin in GM cotton planted. This meant that farmers who had paid premium prices for the GM Bt cotton seeds had, if they could afford it, to apply extra pesticides to combat this secondary pest. In the first nine months of 2007 over 800 cotton farmers in India committed suicide, deeply in debt and in despair at not being able to provide for their families<sup>2</sup>.

**No commercially-available GM plant developed to date has increased yield, enhanced nutritional qualities, can resist drought or is salt tolerant.**

Insect-resistant cotton has a poor performance record in many parts of the world, particularly during extremes of temperature experienced in China and Australia<sup>3</sup>. In Argentina, average cotton yields were higher from 1987-96, the decade before GM cotton was introduced, than they have been since<sup>4</sup>.

Studies of Roundup Ready soya, the most widely planted GM crop, suggest that it has on average 5-

10% lower yield than equivalent conventional varieties<sup>5</sup>.

Meanwhile, researchers have been trialling drought-tolerant and disease-resistant pearl millet varieties developed through marker-assisted selection<sup>6</sup>. Pearl millet is an important subsistence crop for millions of farmers in agriculturally marginal areas.

Scientists in the Philippines are using marker-assisted selection to develop a non-GM rice that can tolerate several days' complete submersion, for example during flash floods<sup>7</sup>.

Scientists say the greatest hope to develop new crop varieties to meet future challenges of increased salinity, drought and other problems is expected to be through conventional plant breeding and marker-assisted selection techniques.

**Farmers are taken to court if they save seeds for replanting.**

Monsanto sues several hundred US farmers a year for saving seeds collected from its GM plants. In court judgements farmers have been forced to pay Monsanto over \$21 million. A much larger amount of money – up \$160 million – is estimated to have been paid in out-of-court settlements<sup>8</sup>.

**GM crops do not solve hunger or poverty**

Soya and cotton, the most widely planted GM crops, are grown on industrial-scale farms for export to rich countries as animal feed and fibre; they do not address rural poverty and hunger either at source or destination. On the contrary, large scale GM plantations threaten production of staple food crops and local livelihoods<sup>9</sup>.

Industrial-scale farming develops at the expense of small farms growing diverse produce for local needs. The percentage of the population living in poverty in Paraguay, which has seen a rapid expansion in the cultivation of GM soya, rose from 33.9% to 39.2% between 2000 and 2005<sup>10</sup>. Soya plantations now cover more than half of cropland, and 90% of this is genetically modified. Up to 100,000 small farmers have been evicted from their lands since the start of the soya boom in Paraguay.

*"Seeking a technological food fix for world hunger may be... the most commercially malevolent wild goose chase of the new century."  
Dr Richard Horton, editor-in-chief of The Lancet.*

### Countries that refrain from planting GM crops are subject to undue pressure

After Zambia rejected America's surplus GM maize (as food aid) in 2002, a US ambassador said the country's leaders should be tried for "the highest crimes against humanity"<sup>11</sup>. Three years later the drought-stricken country reported record maize harvests with an export surplus. No GMOs have been grown<sup>12</sup>.

In Brazil in October 2007 security guards employed by the agrochemical firm Syngenta shot dead a member of the Landless Rural Workers' Movement (MST) during a protest at a biotech crops research facility<sup>13</sup>.

### Growing consolidation threatens choice and pushes up prices

In 2006 the top 10 seed firms controlled 20% more of the seed supply (57%) than they had done just 10 years earlier<sup>14</sup>. Rising prices due to consolidation combined with reduced variety are cutting choices available to farmers.

Four companies – Monsanto, DuPont-Pioneer, Syngenta and Bayer – sell 41% of commercial seeds globally. Monsanto has a virtual monopoly: its GM traits are found in 86% of biotech crops globally.

Recently, the UN conducted the International Assessment of Agricultural Science and Technology for Development<sup>15</sup>. This is the equivalent for agriculture as is the IPCC report for climate change. The UN Synthesis Report concludes that genetically engineered crops are not a solution for poverty, hunger or climate change.

### Growing or importing GM crops does not reduce food and animal feed prices.

It is widely acknowledged, including by the United Nations' Food and Agriculture Organisation (FAO) that a combination of many factors lead to the increase in food and feed prices. These factors include overall increased demand, poor weather conditions and the rapid expansion of agrofuels (also known as biofuels).

Price increases have occurred across the globe, even in the US, with the most permissive GM regulation. The rising prices are unrelated to GM crops.

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Greenpeace campaigns for GM-free crop and food production that is grounded in the principles of sustainability, protection of biodiversity and providing all people with access to safe and nutritious food.

Genetic engineering of crops is an unnecessary and unwanted technology that contaminates the environment, threatens biodiversity and poses unacceptable risks to health.

We are not opposed to biotechnology in itself nor to the use of genetic engineering for the development of medicines or in other research processes, however Greenpeace opposes the release of genetically engineered crops into the environment.