

## **European Commission regrets US decision to file WTO case on GMOs as misguided and unnecessary**

*The US announced today their intention to request WTO consultations on the EU's authorisation system for genetically modified organisms (GMOs). The European Commission regrets this move as legally unwarranted, economically unfounded and politically unhelpful. EU Trade Commissioner Pascal Lamy said: "The EU's regulatory system for GMO's authorisation is in line with WTO rules: it is clear, transparent and non-discriminatory. There is therefore no issue that the WTO needs to examine. The US claim that there is a so-called "moratorium" but the fact is that the EU has authorised GM varieties in the past and is currently processing applications. So what is the real US motive in bringing a case? "David Byrne, EU Commissioner for Health and Consumer protection stated: "We have been working hard in Europe to complete our regulatory system in line with the latest scientific and international developments. The finalisation process is imminent. This is essential to restore consumer confidence in GMO's in Europe." Mr. Byrne recalled that it is the lack of consumer demand for GM-products that accounts for the low sales of GMOs in the EU market. "Unless consumers see that the authorisation process is up to date and takes into account all legitimate concerns, consumers will continue to remain sceptical of GM products." EU Commissioner for the Environment Margot Wallstrom added: "This US move is unhelpful. It can only make an already difficult debate in Europe more difficult. But in the meantime, the Commission strongly believes that we in Europe should move ahead with completing our legislation on traceability and labelling and on food and feed, currently before the European Parliament. We should not be deflected or distracted from pursuing the right policy for the EU."*

### **The EU stance on GMOs is in line with WTO rules**

The EU wants to address the challenges posed by modern technologies of genetic modification. Its regulatory system provides a reliable framework for GMOs in the EU, meeting demands for human and animal health and the environment in the EU. Under the EU system, the prospective effects of GMOs on human, animal and plant health and the environment have to be scientifically assessed before being approved for marketing. Under the EU system, companies intended to market GMOs in the EU must first submit an application to a Member State including a full environmental risk assessment. The assessment is sent to the European Commission who circulates it to all other Member States. In case of objections the European Commission seeks an opinion from the Scientific Committee (and the European Food Safety Authority in the future) and takes then a decision. A total of 18 GMOs have already been authorised in the EU.

Reference is often made to a so-called “moratorium” in the EU on approval of new GM varieties. This relates to the fact that since October 1998, no new GMOs have been authorised for release into the environment due to the fact that the EU’s regulatory regime was incomplete to address the challenges posed by modern technology of genetic modification. This new regulatory framework was adopted in March 2001 and entered into force in October 2002.

The entry into force of these improved rules on approval procedures has enabled biotech companies to submit revised applications for approval of their innovative products. Recently two cotton seed oils for food use have been placed on the market in the EU following authorisation. A number of new applications for marketing of GMOs are at an advanced stage of examination and may therefore be granted over the next months in line with EU legislation.

The EU is also finalising the adoption of rules on labelling and traceability, which aim at responding to citizens’ demands for more and better information on GMOs, and the need to facilitate the freedom of choice between new and more traditional agricultural products. Therefore, the EU system is and will be science-based, not driven by economic considerations.

It must be recalled that the US has so far opposed the Cartagena Protocol on Biosafety, which has been signed by over 100 countries and is intended to ensure through agreed international rules that countries, exporters and importers have the necessary information to make informed choices about GMOs.

The case for appropriate approval mechanisms and marketing regulations has been reinforced by the problems experienced in the US. The “Starlink” case is a clear example of the need for appropriate rules for authorisation and traceability of GMOs. In 2000, GM corn not approved for human consumption was found to have entered in large amounts the US food supply chain; More than 300 product brands had to be recalled from supermarkets by US authorities. In a study of February 2002, the American National Academy of Sciences concluded that there are a number of inadequacies in the way GM plants are regulated in the US.

### **The development argument ignores legitimate concerns of developing countries**

A number of developing countries, including a large number African countries suffering a shortage of food have requested main donors of food aid to avoid providing GMO food. The European Commission finds it unacceptable that such legitimate concerns are used by the US against the EU policy on GMOs. The European Commission believes that it is the legitimate right of developing countries’ governments to fix their own level of protection and to take the decision they deem appropriate to prevent unintentional dissemination of GM seeds.

Food aid to starving populations should be about meeting the urgent humanitarian needs of those who are in need. It should not be about trying to advance the case for GM food abroad (while staying away from the international consensus such as the Cartagena Protocol), or planting GM crops for export, or indeed finding outlets for domestic surplus, which is a regrettable of the US food aid policy.

The European Commission policy is to source food aid for emergency situation as much as possible in the region, thus contributing to the development of local markets, providing additional incentives for producers and ensuring that products distributed closely match local consumption habits.

GM crops of interest to developing countries, such a drought tolerant, acid soil tolerant crops are still in laboratories. Commercially available GM crops are largely dominated by herbicide tolerant crops (75%) and insect resistant crops (17%). However, the use of herbicides on small farmers in poor countries is very limited while insecticides are generally used on commercial crops such as cotton but not on staple crops.

### Some key figures related to commodities market

The US is by far the main maize producer in the world and exports ~20% of its production. However, emerging countries such as Argentina and China have started to compete with the US maize export.

#### 1. Production trade flow of maize (1997 – 2001 average) – Million tonnes

<b>Countries</b>	<b>Production</b>	<b>Net imports</b>	<b>Net exports</b>	<b>Domestic consumption</b>
World	591			
USA	241		47.1	189.9
China	118		5.6	116.9
EU	37.3	2.1		38.9
Argentina	16.1		10.7	5.4
Mexico	18.3	4.9		23.3

(source USDA ERS)

The rejection of GM maize by a growing number of importing countries creates a serious threat to US maize export. In the US, ~35% of the maize is GM maize but only 1-2% of the production is segregated. Therefore, ~98% of the US maize may contain GM maize varieties, many of which have not been approved in other countries. Since the US refuses to implement measures to segregate and control the spread of different GM maize varieties, its exports are affected.

#### 2. Main source of maize main import in the EU 1995-2002 (in tonnes)

<b>Origin</b>	<b>Argentina</b>	<b>US</b>
1995	528 028	3 325 082
1996	584 453	2 045 317
1997	918 790	1 708 445
1998	1 433 829	237 567
1999	2 031 431	30 359
2000	2 238 814	52 635
2001	1 357 138	32 018
2002	1 347 595	25 934

Since 1997, imports of US maize in the EU have largely been replaced with Argentine maize, as some GM maize varieties cultivated in the US are not authorised for cultivation or in the EU. On the other hand, Argentine GM maize producers grow and export approved GM maize varieties and now have a competitive advantage against US producers.

### 3. Origin of soybean import in the EU 1995-2002 (tonnes)

Origin	USA	Argentina	Brazil
1995	9 811 570	2 081 522	3 073 057
1996	8 571 884	1 288 060	3 121 094
1997	7 843 877	350 494	4 637 269
1998	6 691 269	1 064 751	5 439 613
1999	6 471 928	960 502	6 105 756
2000	6 908 250	381 482	6 372 400
2001	6 474 057	670 486	9 729 136
2002	5 518 096	1 163 840	8 933 295

In the US, soybean grower cultivates only the GM soybean authorised in the EU. Therefore, they do not have problems of access to the EU market. The decrease of the share of US soybeans reflects, therefore, a loss of competitiveness of US soybean on the international markets.

### Background

WTO consultation and dispute settlement procedures

The first step in a WTO dispute settlement is a request for consultation from the complaining member. The defendant has 10 days to reply to the request and shall enter into consultation within a period of no more than 30 days (unless otherwise agreed by the 2 parties). The consultation should aim at finding a positive solution to the issue at stake.

If the consultations fail to settle the dispute within 60 days after the date of receipt of the consultation request, the complaining party may request the Dispute Settlement Body (DSB) to establish of a Panel (however, the complaining party may request a panel during the 60 day period if the 2 parties considers that the consultations have failed to settle the dispute).

Once the panelists are nominated, the complaining party has normally between 3 and 6 weeks to file its first written submission and the party complained against another 2/3 weeks to respond. Two oral hearings and a second written submission follow. On average a panel procedure lasts 12 months. This can be followed by an appeal that should not last longer than 90 days. In a case such as the one at stake here, the necessity of hearing scientific experts may prolong the timetable.

Time table (with the shortest possible deadlines taken into consideration)

Filing of request by US		Mid May
Consultation	60 days	Mid July
Request for establishment of Panels		immediate
Establishment of Panel	+/-45 days	End August
Appointment of Panelists	20 days	End September
US 1st written submission	3 weeks	Mid October
EC first written submission	2 weeks	Early November

For more information go to:

[http://trade-info.cec.eu.int/europa/index\\_en.php](http://trade-info.cec.eu.int/europa/index_en.php)

[http://europa.eu.int/comm/food/fs/gmo/gmo\\_index\\_en.html](http://europa.eu.int/comm/food/fs/gmo/gmo_index_en.html)

[http://europa.eu.int/comm/environment/biotechnology/index\\_en.htm](http://europa.eu.int/comm/environment/biotechnology/index_en.htm)

## **Current EU legislation in the EU on GMOs**

Community legislation on GMOs has been in place since the early 1990s and throughout the decade, this regulatory framework has been further extended and refined. The EU introduced specific legislation designed to protect its citizens' health and the environment while simultaneously creating a unified market for biotechnology.

### **GMOs for deliberate release in the environment**

Directive 2001/18/EC sets out the rules governing the release of GMOs into the environment. It entered into force in October 2002. It puts in place a step-by-step approval process, based on a case by case assessment of the risks to human health and the environment before any GMO or product consisting of or containing GMOs, such as maize, tomatoes, or microorganisms can be released into the environment or placed on the market.

Under Directive 2001/18/EC, a company intending to market a GMO must first submit an application to the competent national authority of the Member State where the product is to be first placed on the market. The application must include a full environmental risk assessment. If the national authority gives a favourable opinion on the placing on the market of the GMO concerned, this Member State informs the other Member States via the Commission. If there are no objections, the competent authority that carried out the original evaluation grants the consent for the placing on the market of the product. The product may then be placed on the market throughout the European Union in conformity with any conditions required in that consent.

If objections are raised and maintained, a decision has to be taken at Community level. The Commission first asks for the opinion of its Scientific Committees, composed of independent scientists, highly qualified in the fields associated with medicine, nutrition, toxicology, biology, chemistry, or other similar disciplines. If the scientific opinion is favourable, the Commission then proposes a draft Decision to the Regulatory Committee composed of representatives of Member States for opinion. If the Regulatory Committee gives a favourable opinion, the Commission adopts the Decision.

If not, the draft Decision is submitted to the Council of Ministers for adoption by qualified majority or rejection. If the Council does not act within 3 months, the Commission can adopt the decision.

During the notification process, the public is also informed and has access to the publicly available data on the internet: <http://gmoinfo.jrc.it/>

Three complete dossiers have been submitted to the Commission (GM maize NK 603, GM oil seed rape GT 73 GM maize NK 603 x MON 810 – all from Monsanto) . The 3 applications are for import and processing only (not for cultivation).

### **GM foods**

Regulation (EC) 258/97 on Novel Foods and Novel Food Ingredients sets out rules for authorisation and labelling of novel foods including food products containing, consisting or produced from GMOs.

The first step of an authorisation procedure is an assessment of an application to market a GM food product by the Member State where the food is to be first placed on the market. In case of a favourable opinion, this Member State informs the other Member States via the Commission. If there are no objections against the application, this Member State can authorise the product for marketing in the entire EU.

If there are objections by other Member States, a decision at Community level is required. The Commission consults the Scientific Committees on matters relating to public health and adopts a decision after receiving a favourable opinion from the Regulatory Committee composed of Member State representatives.

As a derogation from the full authorisation procedure, the Novel Foods Regulation provides for a simplified procedure for foods derived from GMOs but no longer containing GMOs, which are "substantially equivalent" to existing foods with respect to composition, nutritional value, metabolism, intended use and the level of undesirable substances. In such cases, the companies only have to notify the Commission when placing a product on the market together with either scientific justification that the product is substantially equivalent or an opinion to the same effect, delivered by the competent authorities of a Member State.

Under the Novel Food Regulation, there are two applications at an advanced stage of the approval process, (one for Monsanto GA 21 maize, and one for Syngenta Bt 11 sweet maize) that are almost ready for a decision. The European Commission is working with both companies with a view to clarifying a number of pending issues.

Last December, the Commission informed MS that cottonseed oil from two Monsanto GM cottonseeds have been placed on the market under the simplified procedure of the Novel Food Regulation (the Regulation provides that when substantial equivalence is established, applicants have only to notify the placing on the market to the Commission). The two cottonseed oils are not distinguishable from their conventional counterparts.

Another new application under Novel Food (for Monsanto GM Maize NK 603) is currently being examined by the EU.

## **EU Rules on traceability and labelling**

The EU recognises the consumers' right for information and labelling as a tool to make an informed choice. Since 1997 labelling to indicate the presence of GMOs as such or in a product is mandatory. From 17 October 2002 onwards Directive 2001/18/EC foresees that Member States shall take all necessary measures to ensure a labelling of GMOs as or in products at all stages of the placing on the market.

The Novel Foods Regulation provides for the mandatory labelling of foods and food ingredients which contain or consist of a GMO without prejudice to the other labelling requirements of Community law. The labelling requirements for foods produced from GMOs, but no longer containing GMO are based on the concept of equivalence.

Council Regulation (EC) 1139/98 lays down provisions for the labelling of foods and food ingredients derived from one maize and one soya variety based on the presence of DNA or protein resulting from genetic modification. This criterion serves as a model providing the rules applicable to labelling of all foods and food ingredients derived from GMO.

In January 2000, the Commission adopted Regulation (EC) 50/2000 ensuring that also additives and flavourings have to be labelled if DNA or protein of GMO origin is present in the final product.

The Commission has recently adopted two common positions (1) on GM food and feed and (2) on Traceability and Labelling of GMOs. These common positions are in the process of being examined by the European Parliament and the Council and expected to be adopted by the end of the year. Indeed, second readings are planned for July.

### **International regulatory framework for GMOS**

All international agreements such as the WTO Sanitary and Phytosanitary Measures (SPS) Agreement, the WTO Technical Barriers to Trade (TBT) Agreement) and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity recognise the right to their members to take the measures at the levels they consider appropriate, for example to protect human or animal health or the environment.

The Cartagena Protocol to the Biodiversity Convention regulates the transboundary movements of GMOs. It has been signed by 102 countries including the European Union. The US is not a party to the Biodiversity Convention and therefore has not signed the Biosafety Protocol. The Protocol will come into force after ratification by 50 countries (41 countries have ratified it at the end of January 2003), including the European Community). It will be legally binding for the countries that will ratify it and countries that have signed it are expected, under international law, to act in good faith and not to take measures which could contradict its objectives.

The Protocol establishes an Advanced Informed Agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import into their territory of GMOs intended for deliberate release into the environment (this includes all vegetative parts that are meant for planting such as seeds). However, the AIA procedure does not apply to GMOs which are for human consumption (food), for animal feeds or for processing. For these, relevant information has to be provided to the Parties through the Biosafety Clearing House (a mechanism set up by the Protocol to facilitate the exchange of information on GMOs, including national regulation pertaining to them, and to assist countries in the implementation of the Protocol). Moreover, these commodities, when exported, must be accompanied by documentation specifying that they "may contain" GMOs and that they are not intended for intentional introduction into the environment. The Parties shall decide on the detailed requirements for this purpose, including specification of the identity of the GMOs and any unique identification.

The US is the largest agricultural commodity exporter but also the largest GM crops producer. In 2002, the US has grown more than 35 million hectares out of the 58 million hectares of GM crops cultivated world wide. The US opposes the biosafety protocol because the enforcement of the protocol will interfere with the main US agriculture commodity exports, i.e. maize and soybeans. However, if the US were to follow the Biosafety Protocol, they would have to specify that food aid might contain GMOs if that was the case, for example.

Several countries have adopted a case by case authorisation process for GMOs but authorisations are not always synchronous with US approvals. Others, such as Sri Lanka, which have not yet adopted a regulatory framework, have banned the import of GMOs. Even China, which has one of the largest biotech industry is now taking a cautious approach with the authorisation of GM food.

Because US traders refuse to segregate, the US maize and soybean face difficulties on the international market because of the possible presence in shipments of GMOs that are not authorised in the importing countries. In addition, due to consumers' concerns over the safety of GMOs, the food and feed industry is increasingly looking for supply of non GM maize and non GM soybean. For those reasons, the US has a vested interest in an international deregulation of GMOs trade and in a non labelling policy of GM food and feed.

The EU has developed a comprehensive regulatory framework for GMOs and for GM food and feed including traceability and labelling provisions. Many countries are now looking at the EU policy to develop their own policy. The US fears that several countries will adopt a similar approach as the EU to regulate GMOs and GM food and feed products.

### **GMOs and food aid**

A number of developing countries, especially in Africa face a humanitarian crisis as a result of adverse weather conditions.

The US has committed to supply 499 000 tonnes of maize grain as food aid between September 2002 and March 2003. In the US, 35% of the maize is produced from GMOs. However, only 1 to 2% of the harvest is segregated (due to the cost of segregation, such maize is more expensive than non-segregated maize). Therefore, US maize is likely to contain GMOs.

Some African countries in the region have initially refused to take the maize for a combination of reasons, namely human health concerns, environmental consideration, the risk of spread of transgenes into their own maize production, and the repercussion such a spread could have on regional and international trade and Intellectual Property Rights concerns.

Following the Zambian ban on GMOs, the US has sponsored a study trip for Zambian scientists in the US and in a number of European capitals. The Zambian scientists have met the European Commission services and have been provided with copies of all scientific assessments from the EU scientific committees (all opinions are favourable).

In their report, the Zambian scientists still argued against the introduction of GM maize in Southern Africa. The Zambian government has confirmed its decision to ban GM maize in the light of the report of the Zambian scientists.

Other countries (Zimbabwe, Mozambique, Malawi) eventually accepted US maize provided that it is milled, which is a process preventing the release of GMs into the environment (their initial ban relates to environmental concerns). But the US has refused to fund the milling.

The US is blaming the EU for the African refusal of the US maize. However, the Commission has repeatedly said that there is no reason to believe that GM food is inherently unsafe to human health. However, developing country governments have the legitimate right to fix their level of protection and to take the decision they deem appropriate to safeguard their territory from unintentional dissemination of GM crops.

With respect to food aid, the Commission policy is to source food for emergency situation as much as possible in the region as this contributes to the development of local markets, provides additional incentives for producers and ensures that products distribute closely match local consumption habits. The US policy is to provide food aid in kind and use surplus production.

For practical reasons and to respect the choice of beneficiary countries, the Commission has requested the World Food Programme to purchase only conventional (non GM) maize for distribution as food aid. This avoids food aid being rejected, the cost of milling (in the case of Zimbabwe, Malawi and Mozambique) and difficulties during the transit of countries like Mozambique that have taken action against the transit of GMOs in their territory.

Food aid is being distributed. In Zambia, the Commission has allocated € 20 Million to the WFP for regional purchase of maize. By mid January 174,000 tonnes out of the 277,000 committed by the EU has been purchased - 99% has been procured in the region (70% South Africa, 23% Malawi, 7% Tanzania and less than 1% in the EU).