The European Union's new labelling rules for genetically engineered food and feed

Implications for the market of GMO and non-GMO products

GREENPEACE

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New labelling and traceability rules within the EU

The European Union's new Regulation on genetically engineered (GE) food and feed[1] together with the regulation on traceability[2] were finally adopted on July 2nd 2003 by the European Parliament. These regulations will substantially change the rules and practicalities of labelling genetically modified organisms (GMOs) in products for human consumption and animal feed. This first comprehensive labelling regime will also set global standards as they apply to the largest single market world-wide. The major changes are:

1. **All products containing or consisting of or derived from an ingredient, which contains more than 0,9% of GMO must be labelled "this product contains genetically modified organisms" or "this product is produced from genetically modified organisms".**
   Additional labelling may be required if the nutritional properties of the product are different from its natural counterparts or where the genetic modification may give raise to ethical or religious concerns.
2. **Labelling is also required where the specific DNA or protein of the GMO can no longer be identified in the final product.**
3. **GMO in animal feed and additives will also have to be labelled.**

The Regulation will be confirmed by the Council of Ministers and enter into force 20 days after publication, probably in August. They will take effect on the market around six months later, most likely in March 2004.

Food and feed processors, trade and retailers have already begun to implement the new regulations and will require their suppliers to comply with their subsequent private quality and traceability standards and certification schemes. This may also result in global certification standards and trade specifications for non-GMO commodities and other agricultural products, especially regarding maize, soya, rape seed (canola) and eventually wheat, should GE wheat varieties be commercialised in the USA, Canada or other countries.

New threshold: 0,9 % of any ingredient

The maximum threshold for GE contamination ("adventitious or technically unavoidable presence"), which is exempted from labelling requirements, has been lowered from 1% to 0,9%. This percentage refers to each ingredient used in the product, not to the mass or volume of the product (e.g. 0,9% of lecithin used, which itself may only account for 1% of a chocolate bar).[3]

It is also important to note that this level only applies if the operator can prove that he has taken all appropriate steps to avoid such contamination.[4]

These thresholds only apply to GMOs which are approved under the Food and Feed Regulation and in accordance with Directive 2001/18 on the deliberate release of GMOs into the environment.[5] Three year transitional exemptions are made for a few GMOs, which are not approved but have benefited from a favourable opinion of the EU Scientific Committee(s) before this regulation entered into force. Such GMOs may be accidentally present up to 0,5%.

Process-oriented labelling of oil, starch, sugar etc.

Labelling of genetically modified food and feed shall also be required for products in which the DNA or specific protein of the GMO can no longer be detected, but which are produced from GMOs.[6] A distinction is made between products which are produced <u>from</u> GE materials and have to be labelled,

and products, which are produced with GMOs (e.g. enzymes, vitamins, GE processing aids and also products from animals fed with GMOs) do not require labelling under this regulation.[7]

Products affected by this new definition, which did not have to be labelled before, include starch, oil, sugar, glucose and alcohol.

An estimated 90% of GE imports to the European Union are used as animal feed and for starch or oil production. These products will now for the first time require labelling as genetically modified food or feed.

New rules and procedures for approval of GMOs in food and feed

With the entering into force of the new labelling and traceability regulations new approvals for the commercial use of some GMOs can be expected within the year. A new approval procedure will apply, which will be executed by the European Unions newly establish European Food Safety Authority, EFSA.[8]

Approval can be sought for food and feed use of specific GMOs as well as for foods containing or consisting of specific GMOs. It will require detailed risk assessment regarding the safety for human and animal consumption and in cases where the GMO will also be released into the environment additional environmental risk assessment (which is detailed in EU Directive 2001/18[9]). These shall be carried out by the EFSA and result in an opinion from the EFSA regarding the safety of the product. The EFSA informs all national Competent Authorities and may, and in cases of planting applications must seek their assessment. Having received this opinion the Commission shall submit a draft decision to the Standing Committee on the Food Chain and Animal Health.[10] The Regulation authorises the Commission to also take into account "other legitimate factors relevant to the matter", not directly referring to health and environmental risks. If the Committee approves the Commission's decision the approval shall be granted or denied accordingly. Should the Committee not agree with the proposed decision with a qualified majority, the decision will be submitted to the Council of Ministers, who are to decide with qualified majority. The authorisation will be granted only for a limited time period of ten years, after which the approval needs to be reviewed or expires.

What GMOs?

A total number of 19 GMOs were approved under Directive 90/220, (which has now been replaced by 2001/18) prior to the establishment of a de facto moratorium for approvals of GMO commercialisation in 1998. These include four maize lines, Roundup Ready soybeans (not for planting but only for consumption) and three oilseed rape lines. Other approvals cover carnation, tobacco, tests and life vaccines.[11] However, in many cases approved varieties have later been banned in individual member states.[12] For others the final act of approval by the member state has been withheld. These approvals need to be re-evaluated under the new regulation over a transition period.

At present 20 new applications for the placing on the market of GMOs are pending (some for as long as six years). Most of them only apply for use in food and feed, some of them as well for planting. An updated list of all pending approvals is provided by the EU Joint Research Centre.[13] Some of them have already had a favourable assessment by national Competent Authorities and Scientific Committees of the EU. In many other cases national competent authorities have submitted questions and objections to the approval and in other cases the competent authority in charge of the initial evaluation is still not satisfied with the information provided by the applicants and the quality of their assessment and documentation.

General traceability rules and concept

According to the European Commission *"traceability is defined as the ability to trace GMOs, and products produced from them, at all stages of their placing on the market throughout the production and distribution chains, facilitating control and also holding the potential to withdraw products if necessary. The obligation of traceability is designed to facilitate accurate labelling of the final product and to provide the means for inspection and control of labelling claims. It is a direct response to the voices of consumers who have made it clear that they want – and have a right – to make informed choices. This proposal places an obligation on all parts of the distribution chain to provide that information. It also builds on the current EU food-labelling scheme but adds additional provisions to allow for inspection and control of compliance with the current rules and reduces reliance on analytical methods to detect the presence of GMOs."*[14]

The concept of "farm to fork" traceability not only relates to GMO ingredients, but is a general philosophy of the European Union's approach to food safety and consumer information.

As a prerequisite for its authorisation any GMO requires a "unique identifier", i.e. a method to identify and test for the specific GMO, which has to be submitted to the European Reference Laboratory by the applicant. Details of the concept of these unique identifiers still need to be established by the Commission. Work related to GMO identification is carried out by the EU's Joint Research Laboratory and its European Network of GMO Laboratories, ENGL[15], and complemented by the European Committee For Standardisation, CEN.[16]

Operators placing on the market an authorised GMO are obliged to inform in writing receiving operators about the fact that the product contains or consists or is produced from GMOs, and of the unique identifiers assigned to these GMOs. This information must be transmitted to any subsequent operator receiving the product. Records of any such transactions must be kept by the operators for a period of five years.

The concept and the meaning of traceability of GMOs is also discussed at the WHO/FAOs joint *Codex Alimentarius*, where an *Ad Hoc Intergovernmental Task Force On Foods Derived From Biotechnology* had been established in 1999 and will present its recommendations to the ongoing Meeting of the Codex Plenary in Rome (June 30 - July 7th).[17] No agreement has been reached so far on traceability, while an agreement on minimum standards for health risk assessment was adopted in Rome. These principles are to be based on pre-market assessment, performed on a case-by-case basis including an evaluation of both direct effects from the GMO and any unintended effects. Although these Codex principles would not have a binding effect on national legislation, they could be used as a reference in case of trade disputes. Present US regulations may not fully confirm with these standards, especially as regards pre-market testing.

Market situation and impacts

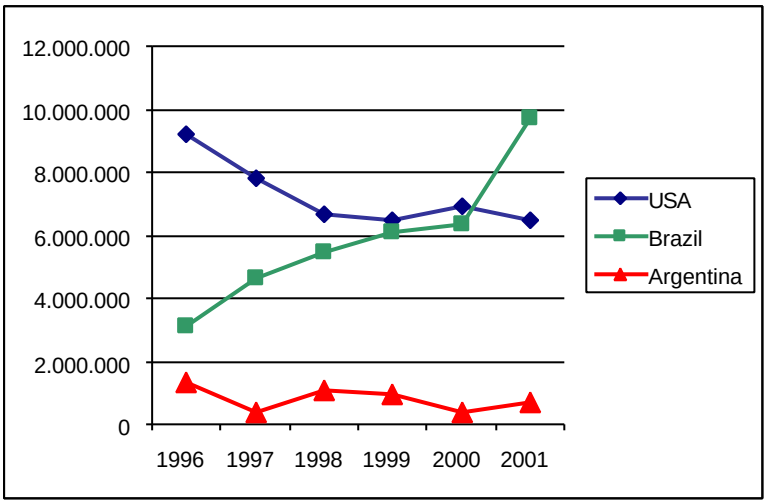
Food and feed ingredients presently affected by GM labelling are mainly soya and maize products. The introduction of GM wheat in the USA and Canada, which has been recently submitted for approval by Monsanto, could have equally massive implications for transatlantic and global commodity trade.

Soybeans

Soybeans, which arrive in bulk carriers, are crushed in a few, centralised facilities into oil, protein preparations, lecithin and a diversity of other products (for a full list of soy products see Annex) as well as animal feed (soy meal and soy cake) which is also directly imported in large quantities.

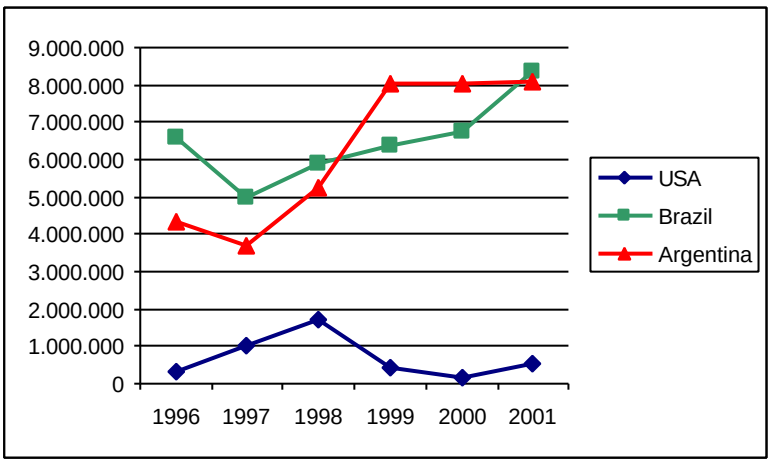
Import of soybeans to the EU in metric tons

Source: European Statistical Office



Import of soy meal and cake to the EU in metric tons

Source: European Statistical Office



Soybean imports are by far the most significant in terms of quantities and value. The EU is the largest import market for soybeans and meal in the world.[18] Soybeans account for over 40% of all EU feed imports[19] and for nearly a quarter of all US agricultural exports to the Community.

Soya is also the most significant GE ingredient in terms of dispersion throughout the food chain. A single ingredient derived from soybeans - lecithin - which is used as an emulsifier, accounts for an estimated 80% of potential presence of GE material in products on supermarket shelves. It is yielded after crushing from a small fraction of the crude soya oil. Cleaning methods for lecithin are available, which prevent the detection of DNA in the product. However, with the new traceability regulation, detectability is no longer the decisive point for future labelling. Substantial impacts on this market can be expected.

As major oil and fat processors, such as Unilever, have requested a non-GE supply for EU production already over the past years, most of the oil derived from GMOs was re-exported by European oil mills to Eastern European Countries. However, with the accession to the EU of Poland, Hungary, the Czech Republic and the Baltic States in 2004, labelling laws will also apply in these countries.

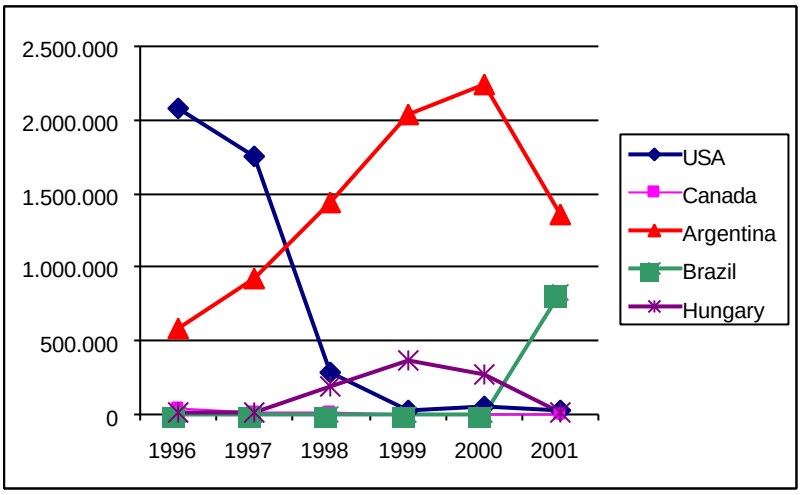
These factors, combined with increased demand for non-GMO feed is a strong incentive for oil mills to increase their non-GMO processing quantities. Many of them at present switch seasonally between US or Argentinean GE imports and Brazilian or other non-GE imports. Cleaning the facility to a degree that allows to stay below the 0,9% contamination threshold is costly and reduces the economic advantage of different sources of import. This may increase the pressure to entirely switch to non-GMO processing.

Maize (corn)

Kernel maize for feed and processing

Import of kernel maize to the EU in metric tons

Source: European Statistical Office



US imports of kernel maize have collapsed to near zero since 1999, due to the fact that some GE varieties grown in the US are not approved for food or feed use within the EU. US officials claim that the 'de facto' moratorium translates into an annual loss of over 300 Mio US$ in maize exports for US farmers. This would be accurate, if the US could regain the entire market share it used to have in 1996.[20] However, price advantages of imports from Argentina (which only allows growing of EU approved GE varieties) and Brazil (no GE varieties approved) may cast some doubts on these figures.

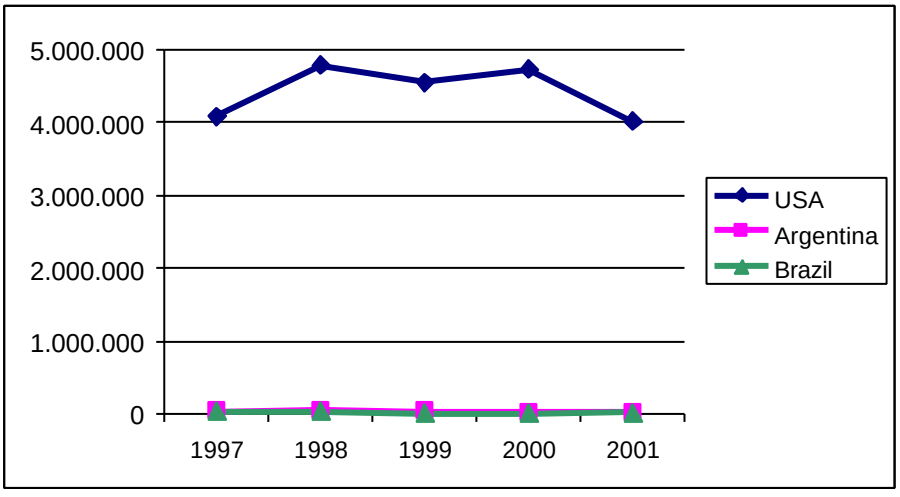
In addition the new labelling regulations will require not only the labelling of GE maize, but also starch and glucose produced from such maize. This will continue to be a major trade barrier for GE maize, even when approvals for additional GE maize varieties will be granted later this year. Some of these varieties which contain antibiotic markers and new proteins may also face opposition from national authorities. The use of antibiotic markers in GMOs is supposed to be phased out within the EU by the end of 2004.[21]

Maize gluten feed for animal feed

The remains of maize after milling and starch extraction are used as cheap sources of animal feed and account for about 10% of EU feed concentrates. Large quantities are being imported to the EU from the USA. While some disputes arose in the past, whether GE maize gluten feed was to be considered a live GMO (some viable kernel seeds usually remain in the mixtures), the new regulations will clearly require labelling of this product.

Import of maize gluten feed to the EU in metric tons

Source: European Statistical Office



Sweet maize for direct human consumption

Sweet maize, mainly canned, some also frozen, is produced by France (300.000 tonnes), Italy (40.000 t) and Spain (20.000 t). Imports from the US have decreased to around 1000 tonnes. Hungary, now accessing the EU Common Market, is a major exporter of sweet maize, competing with France. Consumption had dipped in 1998 due to consumer concerns linking maize to GMOs.[22] No GE sweet maize varieties are presently approved in the EU. However, Syngenta's GE variety Bt11 is a sweet maize variety and might be one of the first GE varieties to be approved, if the present moratorium is lifted. Even though it would have to be labelled, sweet maize producers in Europe are concerned about the potential impact on their products reputation.

"Masa", a special preparation for chip production

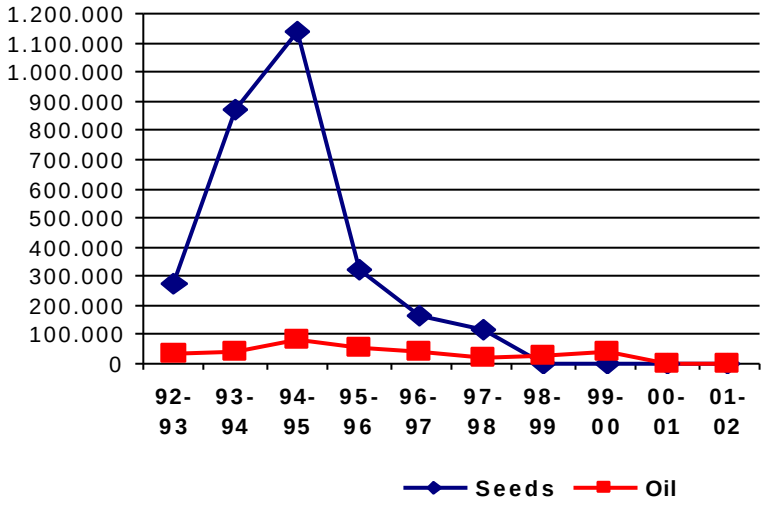
GMOs in maize chips have been one of the first consumer issues in Europe. The special preparation for their production is now available in non-GMO quality both from new European sources and from traditional suppliers in the USA and Mexico, who set up Identity Preservation (IP) systems for this purpose.[23]

Oilseed rape (Canola)

Canadian exports of canola have collapsed since the introduction of GE varieties in 1995/96.[24] The impacts of the new European labelling rules on other international canola markets remain to be seen. Avoiding the use of GE oil in processed foods imported to the EU will be crucial to prevent GE labelling.

Import of Canadian canola seeds and oil to the EU in metric tons

Source: Canola Council of Canada



Also affected by GE labelling requirements is Canadian honey, which increasingly contains GE pollen from canola and would therefore also be required to be labelled as genetically modified.

Other GE crops

Other GE crops, which could be imported, but are of minor economic significance, are cotton oil and fresh or processed Papaya.

Future applications could include potato, tomato (GE varieties of both had been commercialised in the US but were taken off the market again), wheat, beet, sunflower and eventually rice as well as fruits and vegetables.

Consumer attitudes

European consumers remain sceptical about GMOs, especially when it comes to their own foods. Continued surveys of the European Unions Eurobarometer and other sources show a constant rejection of GM foods, even though confidence in benefits arising from genetic engineering technologies seems to increase in other areas.

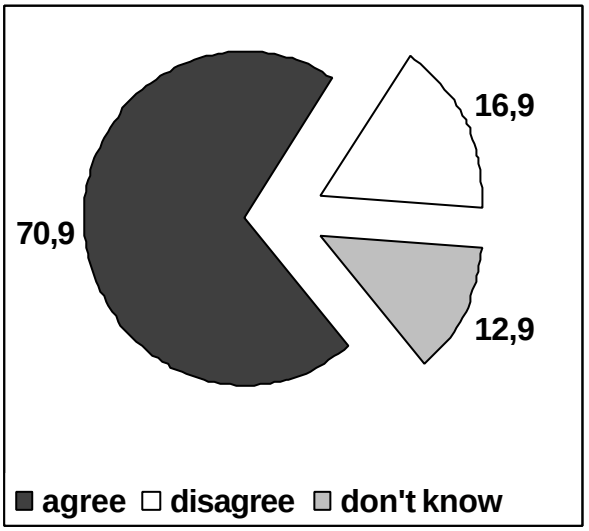
Public attention and sensitivity was especially high in 1996-99, when the first GMOs hit the European market. It has decreased since, after the 'de facto' moratorium on GMO approvals was established in 1998 and nearly all major supermarkets and food brands committed to a non GMO policy. So far, with negligible exemptions and attempts, no GE products appear on European supermarket shelves. As there are currently no GE products in the pipeline which would promise any specific consumer benefits, it is unlikely that this situation will change in the near future.

With the de facto moratorium possibly coming to an end and the US administration's recent aggressive policy on Europe's rejection of GE foods, the level of public awareness may increase and concerns about GMOs in food may rise again. Also, concerns about environmental impacts of GMOs appear to have increased in addition to initial concerns about food safety.

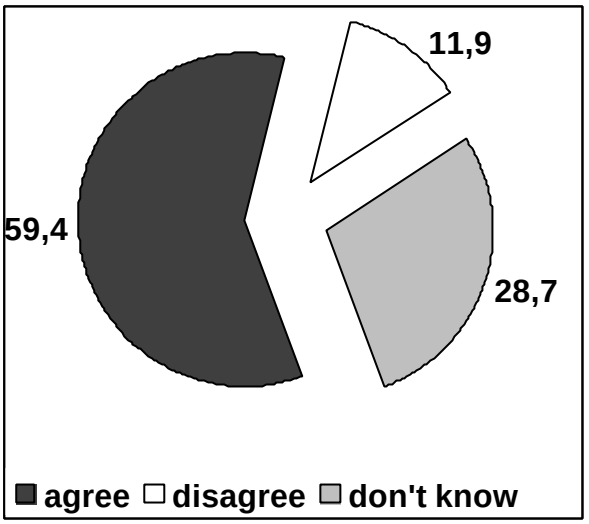
Recent political discussions focus more and more on the issue of whether or not GMOs should be planted within the EU at a commercial scale and how to secure European farmers ability to guarantee non-GE products for their customers in the future. While labelling of products seems to be resolved with the new Regulation, these issues of "co-existence" remain unresolved and fiercely disputed. Special concerns are raised by the organic sector, as its standards categorically exclude the use of GMOs. Cross pollination and seed contamination with GMOs could severely jeopardise the purity of non-GE and organic farm products. Local and regional initiatives to declare communities, counties and districts "GMO free zones" are widespread across Europe and frequently supported by the local authorities. Their number increases despite the fact that the EU Commission has recently stated that GMO free zones would only be acceptable on a voluntary basis.

European consumer attitudes to GE food[25]

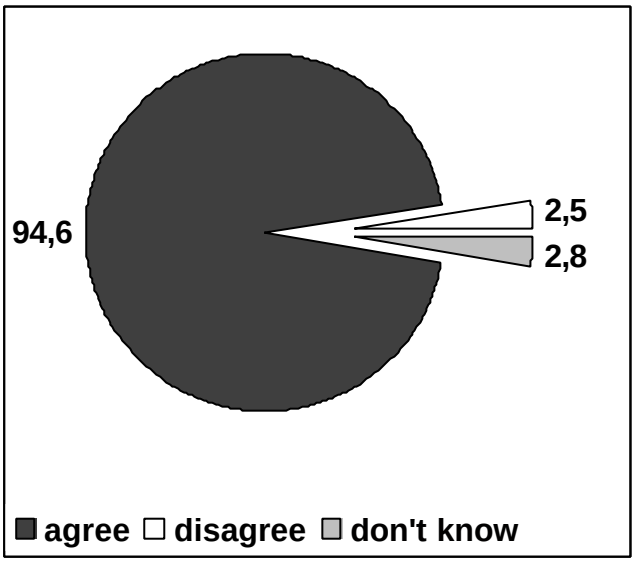
I don't want to eat this type of food



They could have negative effects on the environment



I want to have the right to chose



Source: Eurobarometer 55.2, December 2001

Industry response

Supermarkets

Since 1999/2000 most European Supermarkets follow a non-GMO policy with regard to their own brand products and have not sold any products labelled as genetically modified. In June 2003 the British Retail Consortium, which represents 90 per cent of British Supermarkets, has sent an unequivocal warning to the Government (presently conducting a national consultation on GE crops) that GE food is not commercially viable in the UK.

> **"The customer is where the real power lies. Supermarkets are not going to give shelf space to something that doesn't sell."**
>
> *David Southwell, British Retail Consortium*[26]

In 2001 the BRC had published a comprehensive "Technical Standard For the Supply of Identity Preserved Non-Genetically Modified Food Ingredients and Products"[27]. As a measure of precaution, the detection limits for adventitious presence of GMOs here are set substantially below the thresholds required legally.

It can be anticipated that safety margins well below the allowable thresholds will be imposed on suppliers throughout the food chain by those players who have the market power to do so.

Some supermarket chains, such as Carrefour (EU's No.1), not only impose non-GMO requirements on their suppliers, but actively secure the necessary non-GMO supply in co-operation with their partners.[28]

Major Food producers

Most international and major national brands of food producers have made commitments to their customers not to use GE ingredients. Considerable efforts have been made over the past few years to avoid any necessity to label products as genetically modified. The new labelling rules will entail new challenges for food producers, especially with regard to starch and oil ingredients.

A survey conducted by Greenpeace in Germany reveals, however, that the large majority of the food industry has already prepared systems to comply with these challenges and does not intend to put any products on the market which are labelled as genetically modified. With still more than half a year to go companies who have done their "homework" already include Apollinaris-Schweppes, Coca Cola, Barilla, Campbells, Frosta, General Mills, Karlsberg, Kraft Jacobs Suchard, Procter & Gamble, Unilever. Many others responded to Greenpeace's inquiries that they were presently organising the transition with regard to the new ingredients requiring labelling.[29]

Animal Feed producers

While GE animal feed will have to be labelled in the future, consumer products derived from the use of this feed, such as meat, eggs and milk will not require labelling. Therefor the impact of the new labelling regime on the market remains to be seen. The trend to increase non-GMO imports of soybeans will continue, provided supply, especially from Brazil, remains stable and reliable. Other sources of non-GE soybeans are Canada, India, Paraguay and potentially China.

In addition there are moves within the European Community to partially replace imported soya with other sources of protein that can also be grown domestically as the "Blairhouse Agreement" between the EU and the USA, which puts tight restrictions on EU oilseed subsidies is presently expiring. In this context it is noteworthy that the EU Commission recently decided to open an examination procedure in response to a complaint by the European Oilseed Alliance (EOA) about US soybean subsidies.[30]

Major meat producers, but also some milk and egg producers in Europe have already started voluntary schemes to guarantee non-GMO feeding[31]. Also, some exporters, such as the major Brazilian poultry producers Sadia and Perdigão, have started non-GE programmes.[32]

The BSE crisis and subsequent feed contamination scandals have made animal feed an extremely sensitive issue in the European public. The Commission is presently preparing additional legislation regarding lists of permissible ingredients and HACCP (Hazard Analysis and Critical Control Points) systems for feed producers. Various national and regional voluntary quality programmes attempt to regain consumer confidence. One of the bigger programmes, QS ("Qualität und Sicherheit") in Germany, at present does not exclude GE feed. Criticised by consumer organisations the organising industries argued that the lack of labelling made it too difficult for producers to comply with such a standard. This will change now.

Stringent demands for non-GE ingredients also come from the pet food industry.

The WTO case against the EU's de facto moratorium

In May the US administration took formal steps against the European Union's "de facto moratorium" on the approval of GMOs. After bilateral talks in Geneva collapsed the US will soon request the establishment of a dispute settlement panel, which will then have about a year to judge whether the EU moratorium was or is in breach of WTO rules. The panels decision can be appealed again by the defendant. A final result may be expected in 2005.

The moratorium is based on unilateral declarations of member states that they will not follow the present rules of GMO approvals until substantial improvements are made regarding the risk assessment, labelling and traceability and liability issues. With the adoption of the new Release Directive 2001/18 (which still needs to be implemented by most member states) and the Food and Feed and Traceability Regulations, many of the initial demands of these member states appear to be satisfied. However, liability rules and anti-contamination measures regarding the commercial release of GMOs are still missing. The European Commission argues that the moratorium is about to be lifted or even no longer exists.

The present moratorium is not the major and persistent stumbling block for GMO imports to the EU. Ironically it will be the Food and Feed Labelling and Traceability Regulations designed to finally lift this moratorium, that will prevent marketability of GM products within the EU as it enables consumers to effectively reject these products on the market.

Whether the US will also take the new European labelling and traceability rules to a WTO dispute settlement, remains to be seen. This would be a serious global precedence and a severe challenge of the EU's sovereignty and ability to protect and inform their citizens.

In recent years the USA has threatened countries establishing restrictive GMO legislation with the argument that these contravened WTO rules, usually combined with direct economic and political pressure.[33] A recently passed US bill even goes as far as directly linking aid on combating AIDS/HIV with the requirement that beneficiary nations should accept GE food aid.[34]

The European Union has strong means to counter such pressure. They include a recent decision by the WTO allowing the EU to impose penalty tariffs up to four billion US $ to retaliate against unfair US steel subsidies. This option has not been used so far. The EU decided, in the case of hormone treated beef, to pay penalties imposed rather than respect a WTO decision it does not accept.[35] Continued US pressure on China about its restrictions of GE soybean imports has also yielded no results so far. It was met with firm rejection of the Chinese government, which has adopted labelling rules very similar to the European standards. Smaller and more dependent nations, however, do not have such options.

Under these auspices the transatlantic dispute over GMOs will play a prominent role at the upcoming WTO ministerial meeting in Cancun, Mexico, in September this year.

Entering into force of the Cartagena Protocol on Biosafety

The Cancun WTO ministerial meeting will coincide with the entering into force of the International Cartagena Protocol on Biosafety under the Convention on Biological Diversity.[36] On June 13th, 2003, Palau ratified, as the fiftieth member state, this international agreement on minimum safety standards regarding the transboundary movement of GMOs.

The Protocol, *inter alia*, requires an advance informed agreement for the import of GMOs from one country to another, environmental risk assessments and explicitly establishes the right of member states to refuse such agreement also on the basis of the precautionary principle. This means that the lack of scientific certainty regarding the safety of GMOs for human health and the environment, is accepted as legal grounds to refuse their import.

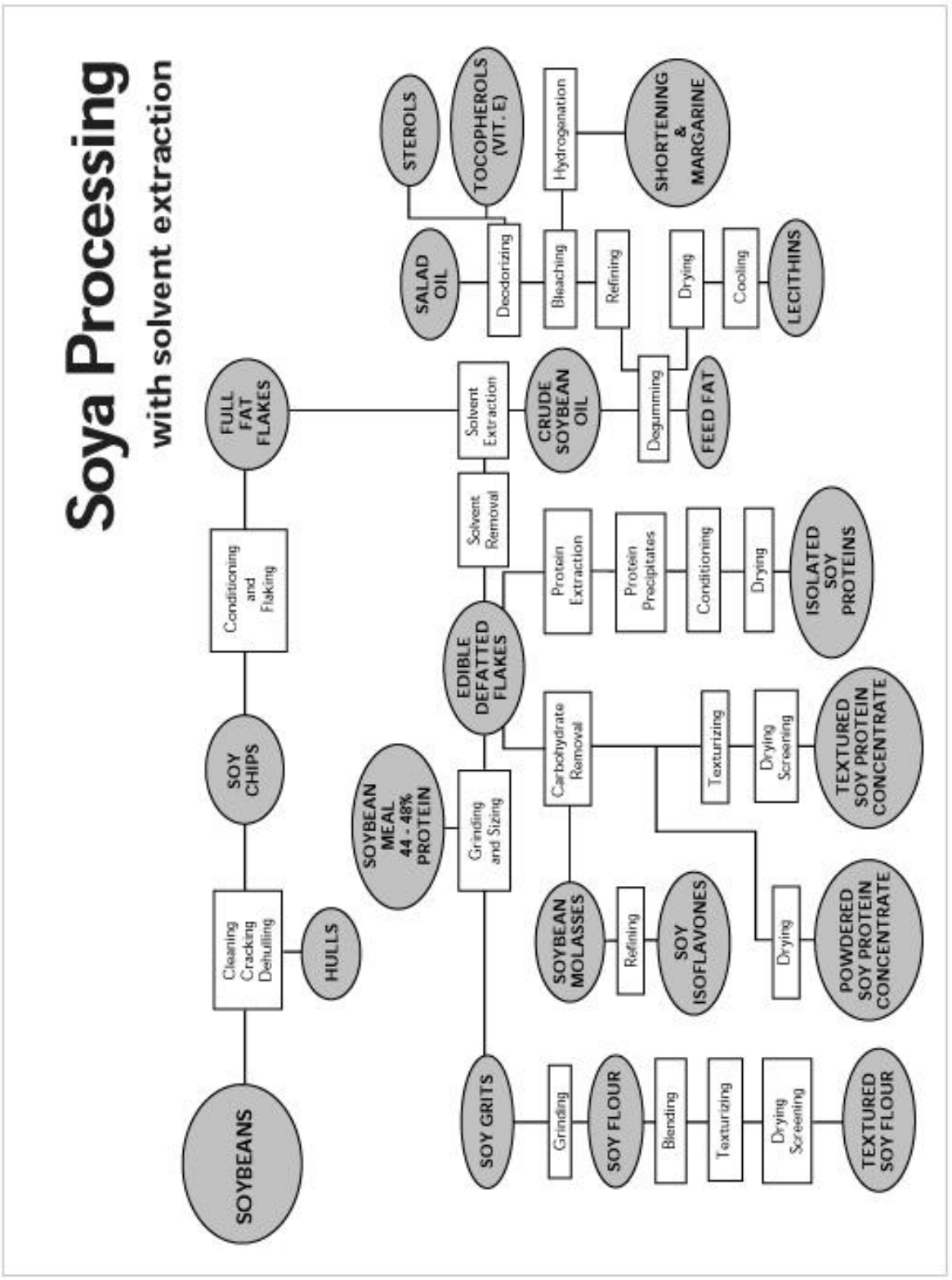
A major dispute during the negotiations of the Protocol was about whether the Protocol supersedes WTO provisions or vice versa. The final text put both agreements on equal level, which could put the UN system of multilateral environmental agreements in direct conflict with the WTO system. The WTO however could also decide to accept the Biosafety Protocol as a reference agreement for their own decisions, as it has done with the Codex Alimentarius and other international agreements. The US case against the EU moratorium is mainly a political move to undermine the "right to say no" enshrined in the Protocol in the run-up to its entering into force. It is seen to aim at many less powerful nations, which have also imposed moratoria and other restrictions on GMO imports.

The signatory states of the Protocol have already agreed to extend the provisions of the agreement to labelling and liability issues within two years of its entering into force. These negotiations will most likely become another "battleground" between the different approaches of the USA and the European Union.

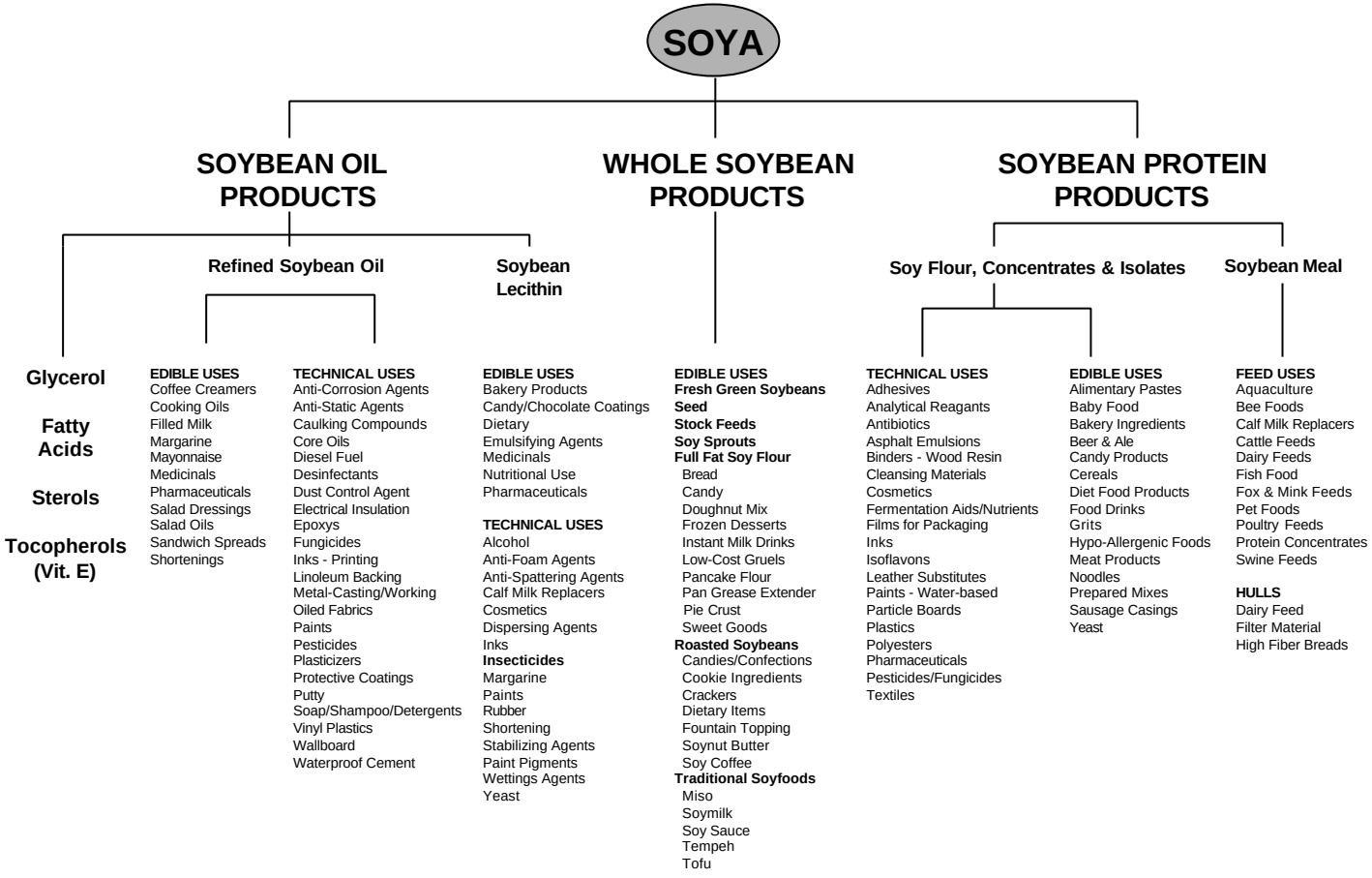
The US has neither ratified the Biosafety Protocol nor the Convention on Biological Diversity and has strongly criticised the precautionary principle, which is also enshrined in the Treaty of the European Union. The Bush administration could be heading for a conflict which appears hard to win. Forcing products upon unwilling countries and their citizens may resonate with some domestic agricultural constituencies in the short run. It is certainly not a smart and promising way to win markets, as long as these are free.

Annex 1: Soya Processing and Soya Products

Source: Soyatech, 2002 Soya and Oilseed Bluebook



SOYA PRODUCTS AND USES



Courtesy of the American Soybean Association
adapted from: Soya & Oilseed Bluebook 2000. Soyatech In., 1999

Footnotes and References

1 Regulation (EC)No .../2003 of the European Parliament and of the Council of ...on genetically modified food and feed.

http://wwwdb.europarl.eu.int/oeil/oeil_ViewDNL.ProcViewCTX?lang=2&procid=5457&HighlighType=2&Highlight_Text=modified Hereafter referred to as ***F&F Regulation***

2 Regulation (EC) No …/2003 of the European Parliament and Council on traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC
http://wwwdb.europarl.eu.int/oeil/oeil_ViewDNL.ProcViewCTX?lang=2&procid=5476&HighlighType=2&Highlight_Text=traceability Hereafter referred to as ***Traceability Regulation***

3 F&F Regulation, Section 2, Article 12. 2."*This Section shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 %of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable. to be easily identified and read.*"

4 F&F Regulation, consideration (28) "*In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of the genetically modified food or feed.*"

5 Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC http://biotech.jrc.it/doc/2001-18-EC.pdf

6 F&F Regulation Section 2 Art. 12, 1.*"This Section shall apply to foods which are to be delivered as such to the final consumer or mass caterers in the Community and which:*

(a)contain or consist of GMOs, or

(b)are produced from or contain ingredients produced from GMOs."

And Consideration (22) "*The labelling should include objective information to the effect that a food or feed consists of, contains or is produced from GMOs. Clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, meets the demands expressed in numerous surveys by a large majority of consumers, facilitates informed choice and precludes the potential misleading of consumers as regards methods of manufacture or production.*"

7 *F&F Regulation,* Consideration (17) *"This Regulation should cover food and feed produced 'from 'a GMO but not food and feed 'with 'a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation."*

8 www.efsa.eu.int, established by Regulation (EC)No 178/2002, laying down the general principles and requirements of food law, establishing the European Food SafetyAuthority and laying down procedures in matters of food safety

9 For the state of the art of risk assessment see guidance document for the risk assessment of genetically modified plants and derived food and feed, March 2003, Prepared for the Scientific Steering Committee by The Joint Working Group on Novel Foods and GMOs Composed of members of the Scientific Committees on Plants, Food and Animal Nutrition http://europa.eu.int/comm/food/fs/sc/ssc/out327_en.pdf

10 The Committee is composed of competent representatives of all Member States, who vote with qualified majority. Until 1 November 2004, the date of the entry into force of the provisions in the Nice Treaty the qualified majority is set at 62 votes out of 87 (71%). Member States' votes are as follows: France, Germany, Italy and United Kingdom 10 votes each; Spain 8 votes; Belgium, Greece, the Netherlands and Portugal 5 votes each; Austria and Sweden 4 votes each; Denmark, Ireland and Finland 3 votes each; Luxembourg 2 votes.

For details about the Standing Committee on the Food Chain see their homepage:
http://europa.eu.int/comm/food/fs/rc/scfcah/index_en.html

11 A list is provided by the EU DG Sanco at http://europa.eu.int/comm/food/fs/gmo/list_author_gmo_en.pdf

[12] e.g. Austria, Germany and Luxembourg have imposed a ban on Syngenta's "Bt-176" maize, Austria and Italy have imposed a ban on Monsanto's "MON-810" maize

13 http://gmoinfo.jrc.it/default.asp

14 "GM food and feed: A new regulatory framework ahead on authorisation, labelling and traceability Decision time ahead ", Consumer Voice, Special edition 1, April 2003, From the European Commission's Health and Consumer Protection DG http://europa.eu.int/comm/dgs/health_consumer/newsletter/200305/consumervoice_en.pdf

15 ENGL, The European Network of GMO Laboratories, has been established in December 2002 by the European Commission. Details can be found on their web-site http://engl.jrc.it
http://www.jrc.cec.eu.int/download/press/releases/gmomemo.pdf

An outline of their tasks can be found at: http://eoi.cordis.lu/docs/int_36630.doc

Methods for assured and reliable traceability of all genetic modifications elaborates especially on the task of detecting unapproved GMO varieties in the furture:

http://eoi.cordis.lu/docs/int_28502.doc

The predecessor project QPCRGMOFOOD is present on the web at
http://www.entransfood.com/RTDprojects/qpcrgmofood/Qpcrgmofood.html

[16] European food standardization: Elements for a CEN strategy and action plan-Annex I reference to the CEN standards on GMO testing under development in CEN TC 275 WG11 - Genetically modified foodstuffs- Six projects are currently under development. http://www.cenorm.be/sectors/food/resources/food_strat.pdf

17 Report Of The Fourth Session Of The Codex *Ad Hoc* Intergovernmental Task Force On Foods Derived From Biotechnology, *Yokohama, Japan 11-14 March 2003*
ftp://ftp.fao.org/docrep/fao/meeting/006/y9220e.pdf

General information on the 26th Session of the Codex Alimentarius: http://www.codexalimentarius.net/session_26.stm

[18] SEAFOOD.COM NEWS, February 13, 2003, World soybean consumption rises rapidly as demand for animal and fish feed grows

[19] USDA, July 2002, Livestock feeding and feed imports in the European Union – A decade of change
http://www.ers.usda.gov/publications/fds/july02/fds0602-01/

[20] The value of US maize exports to the European Union dropped from US$ 305.1 mio in 1996 to US$ 2.6 mio in 2002 USDA Foreign Agriculture Service, BIOC Export Commodity database, http://www.fas.usda.gov/ustrade/USTExBico.asp

21 Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC http://biotech.jrc.it/doc/2001-18-EC.pdf

22 See GAIN Report #FR2054, 7/31/2002
"France Processed Sweet Corn French Sweet Corn Jeopardized by Biotech and Hungarian Sweet Corn 2002"
http://www.fas.usda.gov/gainfiles/200207/145783462.pdf

23 In November 2002 Cargill opened £3.85 million state-of-the-art masa flour plant at its Seaforth site in Liverpool, which exclusively provides non-GMO masa for the European market.

24 For details see http://www.canola-council.org/markets/markets.html

25 All Eurobarometers on the public opinion within the European Union can be found at:
http://europa.eu.int/comm/public_opinion/index.htm

26 The Observer, June 8 2003, "Supermarkets tell Blair: We won't stock GM"
http://observer.guardian.co.uk/politics/story/0,6903,972904,00.html

27 BRC/FDF Technical Standard For the Supply of Identity Preserved Non-Genetically Modified Food Ingredients and Products http://www.tso.co.uk/bookshop/bookstore.asp?AF=A10096&FO=38383&Action=Book&ProductID=0117028495

28 For an example see See Carrefour Sustainability report 2002 at http://www.carrefour.com/docs/carrefour_rapport_en.pdf

29 For details see www.greenpeace.de

30 On March 12, 2003, the European Commission adopted a Decision to open an examination procedure in response to a complaint by the European Oilseed Alliance (EOA) about US soybean subsidies. This procedure should be completed within 5 to 7 months of its announcement in the Official Journal. If the examination shows it is warranted, further action could then be taken, including bilateral negotiations or WTO consultations. Full details can be found in Council Regulation 3286/1994.

http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31994R3286&model=guichett

31 Some prominent representatives are "Wiesenhof", Germanys leading chicken producer, Carrefour and its suppliers Cooperl (Frances leading pork producers), Duc-Bourgoin and La Cana, Zaffini and LDC; Danpo, Denmarks biggest chicken producer and Danish Crown, a world leading pork producer.

32 In 2002, Sadia and Perdigão announced that they will eliminate GM ingredients from all their food products, including meat, and introduce additional mechanisms to ensure its supplies are not genetically contaminated. The companies rank among the largest food companies in Brazil and are also respectively Brazil's first and second largest processors and

exporters of poultry meat. In 2000, Sadia and Perdigão together accounted for over 20% of the Brazilian broiler production and 50% of Brazilian broiler exports
http://www.fas.usda.gov/gainfiles/200104/90680478.pdf

Agência Estado, Brazil, September 13, 2002, "Perdigão se compromete a não usar transgênicos"

[33] States which have been under US pressure because of their GMO policies include Egypt, Bolivia, Sri Lanka, Thailand, South Korea, Croatia. For a full assessment of the US strategy also see the briefing "The US war on Biosafety" published by Greenpeace International in June 2003.
http://www.greenpeace.org/international_en/reports/?campaign%5fid=3942

34 *"(...) Sense of Congress relating to food assistance for individuals living with HIV/AIDS. (...) (C) Although the United States is willing to provide food assistance to these countries in need, a few of the countries object to part or all of the assistance because of fears of benign genetic modifications to the foods. (...) 2) Sense of Congress - It is therefore the sense of Congress that United States food assistance should be accepted by countries with large populations of individuals infected or living with HIV/AIDS, particularly African countries, in order to help feed such individuals."*

Bill Number H.R.1298 for the 108th Congress (May 15, 2003) United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Enrolled as Agreed to or Passed by Both House and Senate)
http://thomas.loc.gov/cgi-bin/query/F?c108:5:./temp/~c108JRD6En:e56633:

35 In 1998 a WTO dispute settlement body decided that the EU ban on beef treated with hormones to speed up growth was lacking scientific evidence of detrimental health effects and therefor was an unfair trade barrier. A penalty fee of US$ 116.8 million and additional Canadian $ 11,3 million was imposed on the EU by the WTO on 15 July 1999 allowing the US and Canada to impose 100 percent tariffs on selected European goods. Still the EU ban is not lifted.
http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#bkmk63

36 The Cartagena Protocol on Biosafety homepage can be found at: http://www.biodiv.org/biosafety