

February 28th, 2007

Cabinet resolves position paper on genetic engineering

On February 28th, the German Federal Cabinet issued the position paper "Further Amendment(s) to the German Laws Governing Genetic Engineering– Key Facts for a Fair Reconciliation of Interests", in the version submitted by the Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft (Federal Ministry of Consumer Protection, Food and Agriculture):

Further Amendments to the German Laws Governing Genetic Engineering – Key Facts for a Fair Reconciliation of Interests

Plant biotechnology is a basic innovation that is deployed in various fields of application:

- So-called "red genetic engineering" deals with the use of genetically engineered products in medicine.
- What is termed "green genetic engineering" is a form of biotechnology dealing with plant breeding and the cultivation of genetically modified plants in order to produce food and feedstuffs or, respectively, renewable raw material.
- So-called "white genetic engineering" refers to industrial applications that use genetically modified micro-organisms.

In Europe, Germany is the country with the largest number of biotechnology firms. In 2005, a total of around 500 companies achieved a turnover of approximately EUR 1.5 billion. Most of these firms are active in the field of "red" genetic engineering.

Germany saw 947 hectares of land planted with genetically modified plants in 2006, which had been granted the corresponding license to be introduced and brought to market. This was corn seed of the brand MON810, which has been engineered to resist the insect pest European corn borer. World-wide, approximately 102 hectares of land in 22 countries were cultivated with genetically modified plants (this being primarily soy beans, corn, rapeseed and cotton); 82% of this area is located in the United States, Argentina and Brazil.

The laws have established strict rules for genetically modified organisms (GMOs). Facilities serving genetic engineering tasks are subject to approval by the authorities. Depending on the potential risk involved, the authorities must be either informed by notice of the work done in these facilities to genetically modify organisms, or this work must be registered, or an approval must be applied for. The deliberate release of GMOs (in research and development) and their introduction (marketing) are also actions that require a permit. In this regard, the responsible authorities perform an encompassing evaluation as to the issues of safety and security. Only if it can be expected that no risk exists for human health and the environment may the GMO be deliberately released or, respectively, introduced and brought to market.

Plant biotechnology is a subject attracting significant interest in the general public and is subject to strongly diverging opinions.

Polls done by demoscopic research institutes and by Eurobarometer show that currently, a majority within the populace does not accept genetically modified foods. In this regard, German public opinion hardly differs from that in other European states. Many people harbor concerns that genetic engineering could impair their health or have detrimental effects on the environment. On the other hand, the opinions voiced cover a broad range when the fields in which genetic engineering is applied and the ways in which it is used are differentiated. For example, people view the application of genetic engineering in medicine in a positive light.

The food industry in Germany (farmers, food manufacturers, retail traders) currently offers hardly any genetically modified foods. Where organic cultivation is concerned, this is the result of considerations that deal with the principle of the matter. Likewise, the food industry sees only limited opportunities of selling genetically modified foods. By contrast, genetically modified feedstuffs are used more frequently. According to EU laws, the products made from the meat of animals that have been fed GM feed need not be labelled as being genetically modified.

Many research facilities and plant breeding companies, on the other hand, rely on genetically modified plants. New varieties provide interesting perspectives and are to contribute to issues such as nutrition, health and renewable resources. The most significant areas in which plant biotechnology is used are those in which pest-resistant or herbicide tolerant plants are to be developed. However, a multitude of projects is already pursuing the goal of breeding plants that can sustain environmental stress factors (cold, dryness), or of ensuring a more effective use of renewable resources, or of producing pharmaceutical proteins in plants. The High-Tech Strategy the German federal government promulgated on August 29th, 2006, emphasizes innovations in plant technology and biotechnology, among other fields. The field of innovation dealing with the subject of "Plants: New Paths for Agriculture and Industry" focuses on plant genome research and on plant biotechnology.

In view of the opportunities and risks involved, the task will be to achieve a fair balance. The coalition agreement concluded by the political parties forming the current German government provides that the laws governing genetic engineering are to establish a framework for the further development and use of genetic engineering in all areas of the economy and of daily life. It calls for the regulations of such laws to be designed in a way that they promote the research

into such engineering methods in Germany and their practical application. In keeping with the principle of exercising utmost precaution, the protection of humans and the environment is to remain the first and foremost objective of German genetic engineering law. These laws must safeguard both the freedom of choice enjoyed by farmers and consumers and the coexistence of different forms of cultivation.

For the further amendment to genetic engineering law, the German Federal government has resolved the following key facts:

1. Promote Research

Research in the area of plant biotechnology is to be promoted. This applies both to research into the safety of the methods used and to research for their further development. The research of safety aspects must be an integral component of all research done in this field. The principle of exercising utmost precaution in order to protect people and the environment is one that the German federal government strictly abides by. Critics of green genetic engineering emphasize that the safety of genetically modified plants and food had not been properly investigated. Therefore, these unresolved issues should be addressed.

However, developmental research should also be intensified. Green genetic engineering provides interesting opportunities, among other things in the fields of nutrition, the supply of power and resources, as well as in pharmacological production. Global development will proceed independently of whether developmental research is performed in Germany or not. Innovation is what makes up Germany's strength. This strength should be put to use. And that is why Germany should not withdraw from the development of new, genetically modified plants and leave this field of economic growth to others. Research should not only be conducted in laboratories but should also be pursued in the context of field tests.

One way of advancing research in the field of plant biotechnology would be to grant to science, as a permanent right, the opportunities that the so-called procedural simplification offers, such as, for example, the simplified procedure. This would make the deliberate release of genetically modified organisms for research purposes much easier; and sufficient experience has been gained with such experiments. The development at the EU level of a new procedure, referred to as the differentiated procedure, should be promoted.

The German Federal government has reviewed whether crops bred in the near vicinity of a deliberate release for research purposes that show hybridizations or other traits of such release could be exempted from the requirement of approval as to their being introduced and traded on the market. The European Commission revealed that it would regard such a regulation to be an infringement of European law. Therefore, it may be assumed that the Commission will object to such a provision in the course of the notification process, which will result in a standstill period of six months and the risk of a procedure for the violation of contract.

Such significant risk under European law is to be avoided and the following is to apply instead:

- On the implementation level, the utilization of a neighbor's crops containing shares of GMO from a deliberate release for research purposes is permissible if it is ensured that GMOs will not enter the food and feed chain, and that they will lose their reproductive ability (such as, for example, by means of thermal utilization or as a result of industrial processing).
- According to the current legal situation it is clarified that the GMO user's liability, regardless of negligence or fault pursuant to Section 36a of the Gesetz zur Regelung der Gentechnik (GenTG, German Law on Genetic Engineering), does not cover all of the financial losses that could be connected, in one way or another, to hybridization with GMOs, but that it is limited to the damages resulting from the impacts on the property. It is not intended to amend the law in this regard.
- Detection methods specific to the respectively released GMOs are to be included in the official collection of methods stipulated by Section 28b of the Gesetz zur Regelung der Gentechnik (GenTG, German Law on Genetic Engineering). In this way, procedures by the authorities will be streamlined and legal security in general will be increased.

For deliberate releases financed by public funds of the Federal government, it will be reviewed whether it is possible to cover any events of liability that may be caused by hybridizations from approved releases using Federal funds. The corresponding exemptions from the current practices in the allocation of funds are being reviewed.

2. Pragmatic Handling of Procedures

We wish to simplify procedures considerably where work done in facilities serving genetic engineering purposes is concerned. Facilities for genetic engineering are divided into four safety levels (S1 through S4). In future, when genetic engineering work is performed in genetic engineering facilities of safety level S1, only a corresponding notice will have to be provided instead of such work needing to be registered. The operator may commence the genetic engineering work immediately following such notification. Further genetic engineering work on safety level S2, that is, follow-up work resulting from the approved initial work, shall likewise only be subject to the notice obligation. This notification procedure will entail less strict administrative requirements as to the documents to be submitted, as far as this is possible in accordance with Directive 90/219/EEC.

The Gentechnikgesetz (German Act on Genetic Engineering) permits exemptions from the provisions of the German Act on Genetic Engineering (Section 2 paragraph 2) for genetically engineered microorganisms categorized as safe and used in genetic engineering facilities. This possibility for granting exemptions is used. Additionally, this possibility of exemption is

to be extended to other GMOs that meet the same security requirements and are used in genetic engineering facilities. In so doing, special recording duties may be waived, as is the case with microorganisms, while a specific registration obligation may be introduced. The provisions of the German Act on Genetic Engineering as to liability remain unaffected, as is the case with microorganisms.

The amendment of the law in 2004 has divided the Zentrale Kommission für die Biologische Sicherheit (Central Committee for Biological Safety) into two committees and the number of members has almost been doubled. In view of the practical difficulties that these committees face, they are to be reunited in one representative body, in which context it is to be ensured that the availability to the committee of expert knowledge on outdoor ecology is safeguarded.

The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal Office of Consumer Protection and Food Safety) will establish guidelines to facilitate the approval procedure for research-related deliberate releases.

3. Define Good Agricultural Practice

The very basic pre-requisite for a fair balance of interests is ensuring that sellers and consumers alike have a choice between products containing GMO or that are free of such material. That is why an economic co-existence must be ensured, which term describes the compatible cultivation of genetically modified, conventional and organic crops alongside one another. The German Act on Genetic Engineering sets out merely general provisions as to how a grower of genetically modified plants is to avoid substantial impairment of his neighbors' crops. To facilitate the handling of such provisions, a statutory ruling (Rechtsverordnung) is to define, for the first time in Germany, those aspects of good agricultural practice in cultivating genetically modified plants that are relevant for the economic co-existence.

The part of the statutory ruling applicable for all species of plants is to set out the following requirements:

- A grower of genetically modified plants must contact his neighbors to inform them of the plans he has to cultivate GMOs, and must coordinate his cultivation plans with those of his neighbor. In so doing, he must take into account those cultivation plans of which he is informed within one month.
- A grower of genetically modified plants must exercise due care as regards the crops growing on the field, storage, transportation, harvest, objects used and second growth, and must maintain records.

Provisions specifically geared to certain species of plants are to be established for the cultivation of genetically modified corn. The statutory ruling shall determine a minimum isolation area that is to be maintained between the area on which genetically modified corn is cultivated and the edge of a cultivation area planted with non-genetically modified corn. The obligation to take precautions against any substantial impairment of areas used for the cultivation of seed shall remain unaffected.

In determining such minimum isolation distances, both the growers of genetically modified corn and their neighbors are to be given maximum security against substantial impairments and possible consequences in terms of liability. The minimum distance as stipulated by the statutory ruling must meet the following requirements:

- It must ensure that in practice, the neighbor is not substantially impaired as a matter of principle, and that organic cultivation is also possible;
- It must take account of the specific characteristics that the different plant species have;
- It must be informed by the most recent and up-to-date scientific knowledge [available], in particular the research and development activities pursued by the scientific expert authorities (Ressortforschung) reporting to the Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft (Federal Ministry of Consumer Protection, Food and Agriculture);
- It must be dimensioned such that the cultivation of genetically modified plants in Germany is not factually rendered impossible.

Based on its current knowledge, the Federal Ministry of Consumer Protection, Food and Agriculture believes a minimum distance of 150 meters is appropriate. This isolation value is to also take into consideration the limited experience gained with co-existence in the practical commercial cultivation of genetically modified varieties. With the increasing knowledge gained about the hybridization patterns of genetically modified corn, the isolation value shall be reviewed and adjusted, if applicable. The scientific expert authorities reporting to the Federal Ministry for Agriculture are asked to continue their research and development activities (Ressortforschung) pertaining to co-existence and to report on their results at regular intervals. Compared to the stipulations made in existing or future provisions in other member states of the EU, the value established in this context is in the middle range (cf. Annex).

We wish to open up new opportunities in the Gentechnikgesetz (German Act on Genetic Engineering) so that by way of private arrangements, the requirements as set out in the Act and statutory ruling as regards economic coexistence may be deviated from, in other words so that neighbors may reduce the stipulated isolation distance by mutual consent. However, this may not lead to the required minimum isolation distances not being adhered to where third parties are concerned, or that requirements under the relevant laws are not adhered to.

An important preliminary issue as regards the codification of coexistence measures is formed by the threshold values for labeling GMO content in seeds. Since seeds come in at the beginning of the production chain, the stipulation of such a threshold value constitutes an important decision defining the direction that the issue of coexistence is to take. It is essential that such a threshold value apply uniformly across the entire European Union. When such a threshold value is determined, Germany will advocate a value that is as low as possible while nonetheless being practicable. This value

- Must consider the need for legal security in control and monitoring practice regarding sampling and evaluation;
- Must ensure that the threshold value for labeling food and feedstuff of 0.9% can be adhered to, in which context particular consideration must be given to the fact that there are other ways in addition to seed by which GMOs are introduced into the crop;
- May not establish requirements that cannot be met in practice by the seed sector;
- May not result in a situation in which, due to the potentially existing contamination of the neighbor's crop, the minimum isolation distance serving to avoid substantial impairments that is to be adhered to by the producer of genetically modified plants must be increased to such an extent that the cultivation of genetically modified plants would be possible only in a few regions within Germany.

4. Informing the Parties Affected – Ensuring Transparency

The parties affected have a legitimate interest of being informed once they come into contact with green genetic engineering. However, fields of genetically modified plants have repeatedly been destroyed in the past. The federal government condemns these illegal activities and demands that the discussion on the research and application of this technology be non-violent and oriented by facts.

The interest the public has in being informed is to be taken into account by the following measures:

- The grower of genetically modified plants is to actively inform his neighbors as to such plants being cultivated.
- While the public section of the list of sites will cite only the communal district, each individual voicing an interest [in obtaining more exact information], and regarding whom no facts are known that would indicate that the information will be used to [find and] destroy a field, will be granted information on the field on which genetically modified plants are cultivated; this will apply in particular for the neighbors and the beekeepers in the region.

On the European level, a practical and non-bureaucratic labeling of all products manufactured using GMO should be sought for. This would take into account the demands voiced by consumer protection agencies as to greater transparency for animal products, similar to that existing for plant-based products. Honey is not subject to any labeling requirement since, as a general rule, a potential share of genetically modified pollen in the overall product is significantly below 0.9 %, being either adventitious or technically unavoidable.

5. Putting the Provision as to Liability in more Precise Terms

The Federal Government has acted upon the mandate given it in the coalition agreement to, jointly with the stakeholders [in the industry] (Wirtschaftsbeteiligte), look into an insurance-based solution for any damages that may occur in spite of the rules of good agricultural practice having been adhered to. However, a liability fund to be created by these stakeholders is rejected by plant breeders and biotechnology companies. Lacking sufficient experience that is indispensable to calculate risks [in this field], the insurance industry likewise considers itself unable to provide any coverage at the moment. The trade associations active in the plant cultivation and biotechnology industries instead seek to establish a code of ethics that would serve to reduce the farmers' risks in terms of liability for damages that may not be completely excluded despite good agricultural practice having been complied with.

The principle that any party suffering damage due to the introduction of genetically modified plants is to be compensated for such damage continues to apply. Hence, the liability due to culpable action (damage claim arising under the law of torts) as well as the no-fault liability (claim for compensation pursuant to the stipulations relating to relations between neighbors) remain in place.

In the course of the debate concerning the liability provision as set out in Section 36a of the Gentechnikgesetz (GenTG, German Act on Genetic Engineering), however, participants pointed out ambiguities in terms of interpretation, which should be remedied for reasons of legal clarity. The following more precise wording is to be reviewed:

- The "open offence" (offener Tatbestand) of substantial impairment (as indicated by using the phrase "in particular") shall be replaced by a conclusive list [of constituent elements]; it is not intended to reduce or expand the scope of liability as compared to that given in the law that currently applies.
- It is to be made clear that liability as joint and several debtors will not exceed the cases acknowledged by adjudication. A pre-requisite [for such liability] is that, based on the applicable regulations as to the burden of proof and in accordance with the factual circumstances of the individual case, that is, in particular, the geographical location and size of the respective fields, any one of the neighbors may have caused the substantial impairment, and that [the problem is]

solely that it is impossible to determine which of the neighbors in fact caused such substantial impairment and to what extent, if not in its entirety.

In the course of drafting, debating and promulgating the law, additional scientific expertise is to be called in.

Beekeepers shall not be held liable for the introduction of genetically modified pollen into conventional or organic cultures or fields since honeybee flight cannot be controlled.

6. Guaranteeing the Protection of Nature

In accordance with the principle of exerting utmost precaution, the protection of humans and the environment remains the primary objective of the German laws governing genetic engineering.

To the extent the approval to introduce and trade [GMO products] on the market contains provisions as to the protection of nature and the environment, the GMO user is to inquire with the respective authority responsible for the protection of nature and the environment (Naturschutzbehörde) as to whether a factual situation provided for in said approval applies to the site of cultivation and must therefore be observed.

The practice thus far in place, which is that a flora and fauna habitat compatibility review being performed in accordance with Section 34a of the Bundesnaturschutzgesetz (BNatschG, Federal Nature Conservation Act) is to be oriented by the protective purpose of the respective flora and fauna habitat, or, respectively, the conservation objectives of the respective Natura 2000 area, continues to apply.

Annex

Summary of the existing regulations, and those that are being prepared, as to minimum isolation areas for genetically modified corn in other EU member states

State	Isolation area to neighbors with conventional cultivation	Isolation area to other neighbors
Denmark (statutory ruling)	200 m	ditto
Netherlands (statutory ruling)	25 m	GMO-free/organic: 250 m
Portugal (statutory ruling)	200 m; if an isolation track is cultivated (24 rows of conventional corn): 0 m	organic: 300 m; if an isolation track is cultivated (28 rows of conventional corn): 50 m
Czech Republic (statutory ruling)	70 m; 1 row as isolation track (minimum width 0.7 m) shall replace 2 m of isolation area	organic: 200 m; 1 row as isolation track (minimum width 0.7 m) shall replace 2 m of isolation area; however, there must be at least 100 m of isolation area
Latvia (draft law)	200 m	organic: 400 m
Lithuania (draft statutory ruling)	200 m (and 3 m conventionally cultivated corn as isolation track)	ditto
Luxemburg (draft statutory ruling)	800 m	ditto
Poland (draft statutory ruling)	200 m	organic: 300 m
Slovakia (draft statutory ruling)	200 m; 1 row as isolation track (at least 6 rows) shall replace 2 m of isolation area	organic: 300 m; 1 row as isolation track (at least 6 rows) shall replace 2 m of isolation area
Spain (draft statutory ruling)	220 m (and 4 rows of conventionally cultivated corn as isolation track); in the event of blooming periods being	seed: 300 m

State	Isolation area to neighbors with conventional cultivation	Isolation area to other neighbors
	staggered over time: 0 m (subject to approval by authorities)	
Hungary (draft statutory ruling)	400 m (depending on local conditions 800 m)	ditto