IMPLEMENTATION OF THE EU LEGISLATION CONCERNING GENETICALLY MODIFIED ORGANISMS IN THE GERMAN FOOD AND FEED INDUSTRY

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Implementation of the EU Legislation Concerning Genetically Modified Organisms in the German Food and Feed Industry

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Abstract

The worldwide acreage of genetically modified (GM) plants is growing year by year and amounted to 90 million hectares in 2005. Therefore the European Union implemented a series of legal requirements and regulations which are related to R&D, commercial use and labelling of genetically modified organism (GMO). The food and feed industry is mainly affected by Regulations (EC) No 1829/2003 and 1830/2003 and thus this study aims to analyse the effects of those regulations on the German food and feed industry. The empirical basis was a comprehensive written survey in 2005 with a total of 1700 filled in questionnaires. According to this survey the German food and feed industry is affected of the increasing use of GM plants and the corresponding GMO legislation although no GM plants are commercially grown in Germany. Around two third of the German feed industry already use GM raw materials while 100% of the food factories mentioned to avoid GMOs with labelling obligation. Efforts of complying with the requirements of Regulations (EC) No 1829/2003 and 1830/2003 in food and feed industry mainly result in higher personnel efforts, higher costs of raw materials and additional costs of GMO analytics. In total they can rise up to 1.8% of the turnover in the feed industry, while generally they are below 1 % of the turnover in the food industry. The labelling requirements concerning GMOs are mainly fulfilled in the German food and feed industry according to test results of competent German authorities.

Approach

In contrast to the growing use of genetic modified plants in agriculture, the acceptance of GM food is still low in the European Union (EU) and in Germany (FRANK, 2004). Due to this low acceptance the EU passed regulations to ensure freedom of choice of consumers and users on the EU market. The food industry is mainly affected by Regulation (EC) No 1829/2003 and 1830/2003. These regulations provide a framework of processing and trading GM food in the EU. However, labelling of GMOs in food is required since passing the “Novel Food Directive” in the year 1997: any food product containing more than 1% of GM ingredients was obliged to label, a label which food producer and retailers have strived to avoid. This policy of "substantial equivalence" gave a free ride to highly processed food products where the presence of GMOs is not any more detectable by analytical testing (TRANSGEN, 2005B). Therefore Regulation (EC) No 1829/2003 and 1830/2003, which entered into force in April 2004, obtain exceeded labelling and traceability requirements for GMOs with following key components:

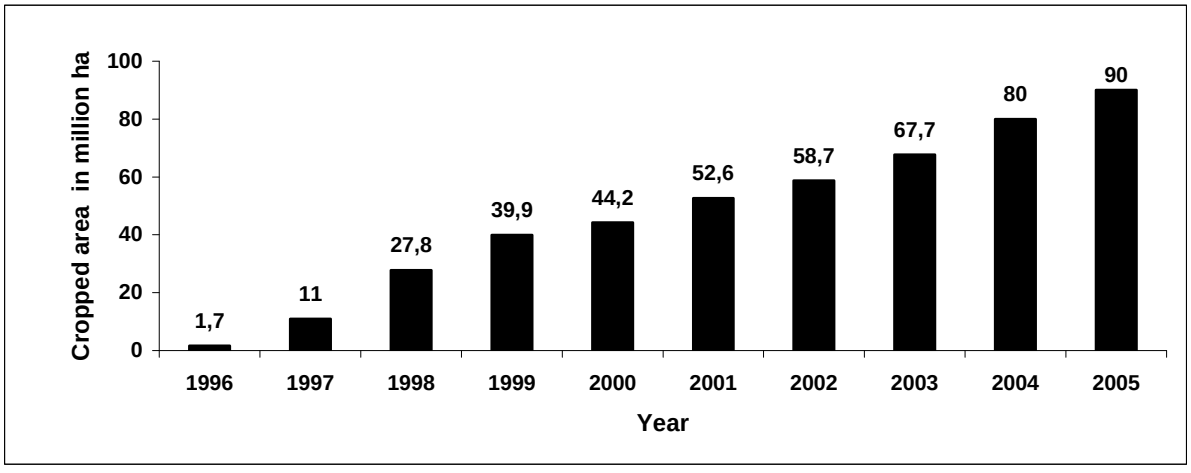
- *Traceability:* Mandates product traceability through documentation and implementation for the entire supply chain.
- *Labelling:* Products containing GMOs must be labelled as such, even when undetectable by tests. Products containing traces of GMOs below the appropriate regulatory tolerances thresholds are exempt from labelling, provided that compliant traceability systems are in place and traces of GMOs are adventitious and technically unavoidable.
- *Thresholds:* 0.9% tolerance thresholds for EU authorized GMOs and 0.5% for unauthorized GMOs if they have already received a favourable EU risk assessment. Compliant traceability systems must be in place and must demonstrate that any traces of GMO are adventitious and are technically unavoidable (FAGAN, 2004).

So far there are no studies available analysing the effects of Regulations (EC) No 1829/2003 and 1830/2003 and how they can be implemented efficiently in the food and feed industry in Germany. To investigate this issue a questionnaire was developed, based on previewing existing literature as well as interviewing experts and representatives of the food industry. The questionnaire was sent to 1,714 factories of the German food industry in May 2005. Emphasis laid on efforts to reach all branches relevant for potential use of GM ingredients by considering different sizes (depending on staff and total revenue) and brand strategies. The number of returns was about 20% and the data gathered in this inquiry were analysed with SPSS.

Cultivation of genetic modified plants

Since their commercial introduction in the USA in 1996 the acreage of GM plants is growing year by year and reached about 90 million hectares in 2005, located in 21 countries. The steady increase of the acreage of GM plants is illustrated in figure 1. Main countries of cropping GM plants are the USA, Argentina, Brazil, Canada and China (CLIVE 2005)

Figure 1: Global area of cultivated GM plants



SOURCES: CLIVE 2005

The commercial use of GM plants focuses mainly on soybean, corn, cotton, and rapeseed. The genetic modification mainly refers to herbicide tolerance and insect tolerance. In 2005 the cropped area of GM soybeans amounted to 54.4 million hectares, this is 60% of the worldwide soy production. Main production countries of GM soybeans are the USA, Argentina, Brazil as well as Canada, Paraguay, Uruguay, Romania, South Africa and Mexico. GM corn was cropped on 21.2 million hectares in 2005. This is 14% of the global corn production. GM corn was cropped in 12 countries included the five EU member countries Spain, Germany, France, Portugal and Czech Republic with a total area of 50,000 ha in 2005. GM rapeseed was grown on 4.6 million hectares in 2005 (18% of global production of rapeseed) mainly in Canada and the USA. In 2005 GM cotton was grown in the USA, China, Argentina, India, Australia, Mexico, South Africa and Columbia on 9.8 million hectares - what results in an adoption rate of 28% of the worldwide cotton production. In 2005 there was first cropping of GM rice on 4,000 ha in Iran and approval of GM rice varieties is expected in China in the near future (TRANSGEN 2005G).

GM cropping and import situation of the German food and feed industry

Because there is nearly no cropping of GM plants in Germany, the main risk of unintended GMO admixture in the food and feed industry results from imports of food ingredients and raw materials which are produced in countries where GM varieties are cultivated. 94% of GM crops were planted in North and South America in 2005. Another 5% of GM crops (mainly GM cotton) were cultivated in China and in India in 2005 (CLIVE 2005). The adoption of GM varieties in the most important crops and countries is presented in table 1.

Table 1: Adoption of GM varieties by country (and year)

Crop	USA	Argentina	Canada	Brazil	Paraguay
Soybean	87% (2005)	98% (2004)	58% (2003)	22% (2004)	60% (2004)
Rapeseed	76% (2003)	-	74% (2004)	-	-
Cotton	79% (2005)	-	-	-	-
Corn	52% (2005)	45% (2004)	50% (2003)	-	-

SOURCE: TRANSGEN 2005A

Because 98.5% of the global acreage of transgenic crops belong to soybean, rapeseed, cotton and corn an overview is given about raw materials and potential sources of unintended GMO admixture in food and feed industry based on these crops:

Soybean

Soybean are an important raw material base in numerous food products, food ingredients and additives It is estimated that about 20,000 to 30,000 food products could be affected by GM soybeans-derived ingredients alone in Germany (MENRAD ET AL. 2003):

- Plant oil fat, soy oil, lecithin and vitamin E
- Soy-flour, soy groats, other soy-protein (in particular in convenience-type food products)
- Traditional soy products like tofu, soy sauce and miso (TRANSGEN 2005F)

Cotton

Several side products are produced during processing cotton fibres. These products can be used as:

- Oil: cotton oil is of high quality and is used as fry oil as well as in margarine.
- Groats: Protein rich groats are mainly used as feed but also as raw material in protein compounds and isolates as well as in cotton milk.
- “Linters”: these very short not spin able fibres (which derive from the cotton seed) are used as thickening agent, stabilizers, or emulsifier in different food products (TRANSGEN 2005C).

Rapeseed

Several different food products are produced directly or indirectly of rapeseed, like:

- Rape oil, as high quality food oil or especially in margarine, but also a big variety of other food products containing plant oil ingredients,
- Feed (protein rich rapeseed cake), as side product of oil production
- Rape honey can contains pollen of GM rapeseed (TRANSGEN 2005E).

Corn

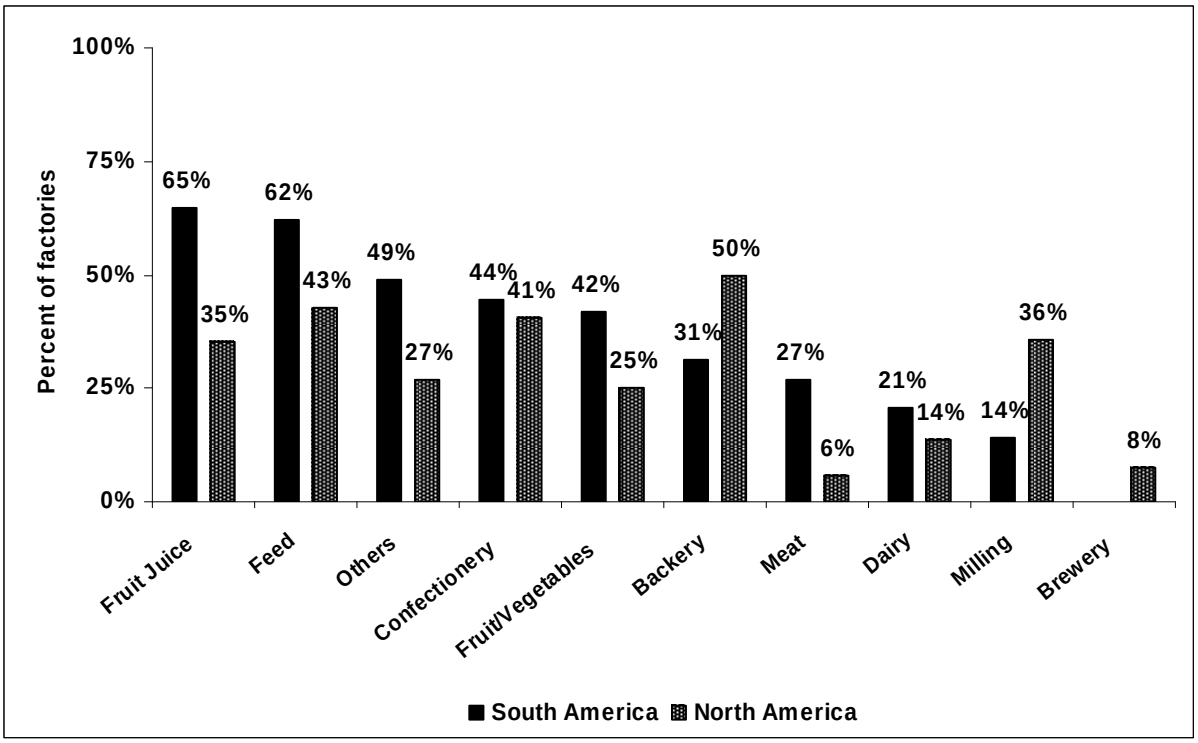
Corn is another of the most important raw materials in many food products.

Thus it is estimated that around 20,000 up to 30,000 food products can be affected by GM corn-derived ingredients in Germany (MENRAD ET AL. 2003), like:

- Corn oil and corn flour bakeries and finger food
- Cornflakes and other cereals
- Alcoholic drinks, like beer
- Starch, modified starchs as well as numerous starch-derived sugars (TRANSGEN 2005H)

In order to get some insight about the pressure of GMOs on the German food and feed industry the survey analysed the proportion of factories which import raw materials from North and South America. This is due to the fact that 94% of all GM crops are grown in this area and obtain already high adoption rates as illustrated in table 1. The proportion of German factories in different branches which mentioned to import raw materials from North and South America are shown in figure 2.

Figure 2: Proportion of German factories by branches which import raw materials from North and South America



SOURCE: OWN INVESTIGATION

German feed factories mentioned fairly often to import raw materials from North and South America. Soy grist and unprocessed soy beans are main import commodities of those regions. EU member countries import year by year around 40 million tons of soybeans thus being the most important soybean importer of the world. They mainly derive from Brazil, USA and Argentina. In these countries there is large scale cropping of GM soybeans as indicated in table 1. Soy raw material imported from USA, Argentina and some parts of Brazil at least partially can consist of GM soybean. Therefore the German feed producers started to label all feed that contains soybean as genetically modified. Considering corn and rapeseed Germany nearly has a self supply rate of 100% (TRANSGEN 2005 I). It is unknown how many by products of cotton production are imported and used in the German feed industry. Ingredients like vitamins, enzymes and dyestuffs are also possible sources of unintended GMO admixture in feed production.

With regard to the food industry fruit juice factories answered most frequently to import raw materials from North and South America. Currently there is no commercial cropping of GM fruits worldwide (except papayas) and therefore unintended GMO admixture by fruit ingredients is not relevant. Unintended GMO admixture with labelling obligation can arise throughout ingredients like vitamins, glucose syrup, fructose syrup or other products of starch saccharification where GM corn was used as raw material base.

Confectionary factories also mentioned quite often to import raw materials of North and South America. Confectionary products are an aggregate e. g. of sugar products, long-life bakery product, cacao products or ice cream. Sources of unintended GMO admixture are glucose syrup and starch of GM corn as well as lecithin or proteins deriving from GM soybean.

Fruit and vegetable processors also import raw materials of the aforesaid regions. There is no GMO pressure of main ingredients, since GM fruits and vegetable are not yet grown commercially, besides GM squash, GM papayas and GM tomatoes on a very limited scale. In fruit and vegetable processing GMO pressure derives from GM soy flour, GM soy protein and GM soy oil, glucose syrup, fructose syrup or other products of starch saccharification in which GM corn is used as raw material.

Meat industry also imports raw materials stemming from North and South America. But EU legislation requires no labelling of animal products (e. g. meat, eggs, milk) produced by using GMOs as feed stuff. Processed meat, as for example sausages, obtain potential GMO admixture throughout ingredients like glutamate.

Since so far no GM crops are commercially grown in Germany there is no risk of potential admixture of GMOs by domestic raw materials. The main sources of unintended GMO admixture result through imports of bulk products (like soybeans, maize or rapeseed and derived ingredients) which are grown in North and South America. In particular feed, confectionary products and bakery

products obtain considerable risk of unintended GMO admixture, related to higher volumes of soy and corn raw materials. If possible, food industry changed to other ingredients without potential GMO admixture in such cases.

Strategy towards GMOs

The main target of regulations (EC) No 1829/2003 and 1830/2003 is to provide freedom of choice between GM and conventional food. Therefore those regulations require mandatory labelling if food and feed contains, consists or is produced from GMOs in a proportion higher than 0.9% of the food/feed ingredients considered individually or food and feed consisting of a single ingredient. The threshold of 0.9% is just applicable if GMOs are authorized in the EU and only in case of adventitious and technical unavoidable admixture. Specific thresholds are necessary because agricultural production as well as the food and feed industry are open systems and therefore it is impossible to totally exclude all traces of GMOs.

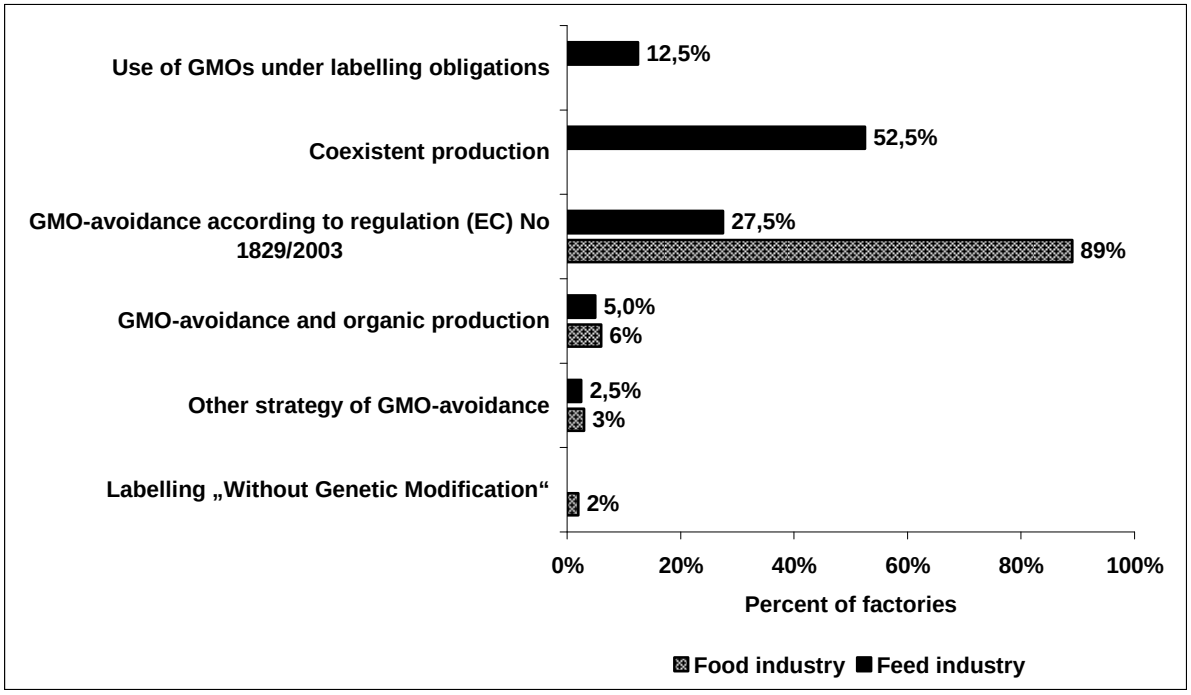
According to our survey results there is no use of GMOs with labelling obligation in the German food industry. But this result does not mean that there is no use of GMOs in the German food production, because Regulation (EC) Nr. 1829/2003 just requires labelling of materials regarded legally as foodstuffs. Supplies (like enzymes), carrier substances (e. g. for aromas or vitamins) or culture media for micro-organisms (like for yeast reproduction) are not regarded as foods from a legal point of view and thus exempted from GMO labelling obligations.

In contrast to the food factories 12.5% of the feed factories mentioned to use GMOs with labelling obligation and another 52.5% answered to use GMOs but also to produce conventional feed in coexistence. One reason for this differing behaviour of the feed industry is the fact that soybean is an important protein compound in feed production which cannot easily replaced by substitutes. In

addition, the prices of GM soybean are lower on world markets compared to non-GM crop. Since there is very limited cropping of soybeans in the EU farmers depend on imports and therefore EU farmers are also affected by the high adoption rates of GM soybeans in the main producing countries. Another reason is the regulatory situation in the EU which does not oblige the labelling of animal products which were produced with GM feed compounds. Therefore the information that the feed was genetically modified does not reach the final consumer and thus does not lead to loss of markets, if consumers would like to avoid such foods.

According to the results of our survey there is not just a single strategy to avoid GMOs in the food industry in Germany. 89% of the food factories mentioned to avoid GMOs under compliance of Regulation (EC) No 1829/2003 (figure 2). Those factories just fulfil legal requirements to avoid GMOs, but do not take any further actions. A higher standard of avoiding GMOs is necessary under the label “Without Genetic Modification”, because users of this label are obliged to take additional efforts in production, like e. g. the avoidance of GM feed compounds. This label is based on German national law and is not compulsory for the food industry - as outlined in the 2% of all factories which follow this strategy. The highest standard of GMO free foods is provided under organic production rules although there is no guarantee that organic food products are totally GMO free. Around 6% of the responding food industry factories realise this strategy. Also in feed industry 27.5% of the factories mentioned to avoid GMOs under compliance of regulation (EC) No 1829/2003. 5% of the feed factories mentioned to avoid GMOs under compliance of organic production rules as it is illustrated in figure 2.

Figure 2: Strategies to fulfil legal requirements of Regulation (EC) No 1829/2003 taken by German food and feed producers



SOURCE: OWN INVESTIGATION

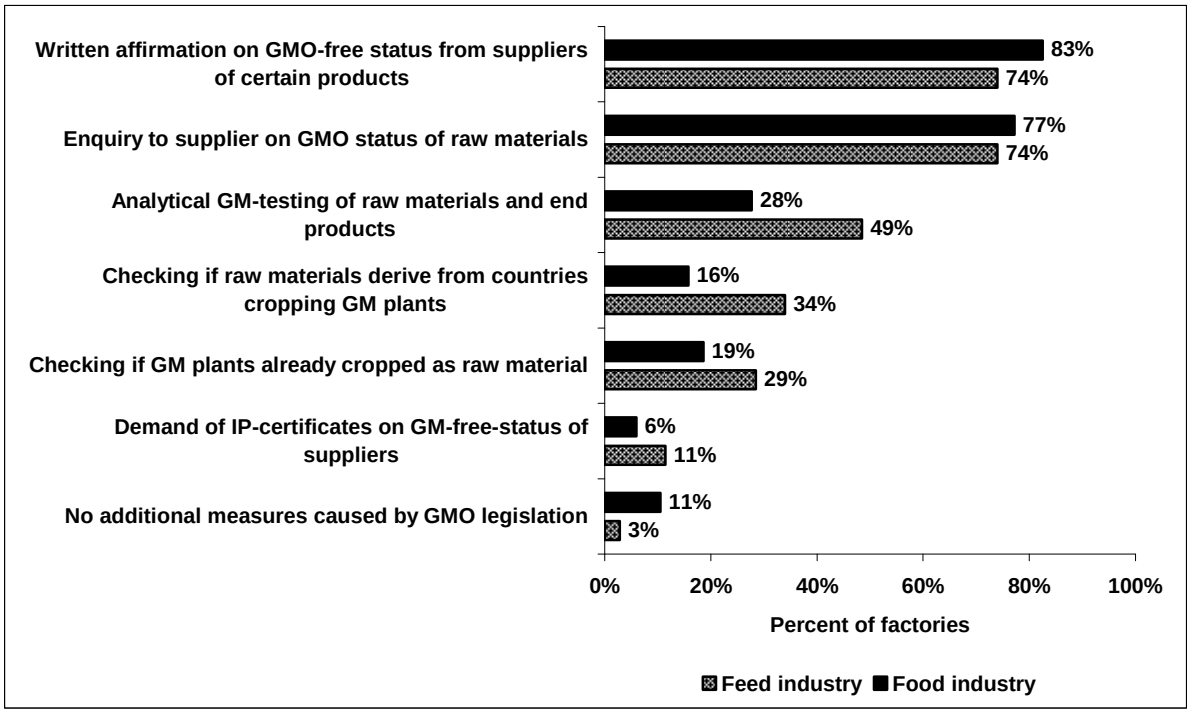
Thresholds of GMOs in the context of Product Liability and Warranty

If GMO contents exceed the legal thresholds of GMO adventitious presence in food products, Regulation (EC) No 1829/2003 and 1830/2003 require that operators have to ensure that this information is forwarded at all subsequent stages up to the final consumer (EC 2003A; EC 2003B). Additionally, article 12 and 47 of Regulation (EC) No 1829/2003 require that "operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid GMOs". This means that in case of detecting GMOs exceeding legal thresholds the burden of proof is shifted: Thus food and feed producers are obliged to submit evidence that they have undertaken appropriate steps to avoid the presence of GMOs in production processes (BLL, 2004). The wording of this article in Regulation (EC) No 1829/2003 is quite general and food producers enquire definitions of "appropriate steps" to comply

legal requirements. Due to this lack of information several institutions of the food industry developed guidelines for their members, according to product liability and warranty with regard to Regulation (EC) No 1829/2003 and 1830/2003.

The results of this survey show that the food industry in Germany is considering different “appropriate steps” in order to comply with articles 12 and 47 of Regulation (EC) No 1829/2003 as it is illustrated in figure 3. Over 70% of the food and feed factories mentioned to demand written affirmation about GMO free status of raw materials and to do enquiries back to supplier concerning the GMO status of raw materials. These measures are rather easy to integrate in existing quality management systems and often seem to be sufficient to fulfil legal requirements. Another suitable measure to exclude GMOs in food and feed production is to check raw materials and ingredients whether theoretically GMO admixture can exist or not: GMO admixture can be excluded in case the used ingredients cannot be produced from GM crops and if raw materials derive from countries without cropping of GM crops. These measures are used by around 19% or 16% or the German food factories respectively (figure 3). Analytical testing is a quite extensive measure to avoid GMOs and it is also to consider that analytical GMO testing is not feasible any more in highly processed food products. According to our survey 28% of the German food producers and 49% of the German feed producers (which mentioned to avoid GMOs) conduct analytical GMO testing. The higher proportion of feed factories which conduct analytical testing can be explained by the fact that the feed industry often uses fairly unprocessed raw materials where analytical testing of GMO content is still possible. As indicated earlier raw materials and ingredients with potential GMO content in the food industry are often highly processed (like oil components) in which GMO detection is sometimes not feasible with analytical tests.

Figure 3: "Appropriate steps" to avoid GMO admixture in food and feed products



SOURCE: OWN INVESTIGATION

Another possibility to exclude GMOs is to demand IP-certificates. These certificates offer a high standard of "Identity Preserved" GMO free raw materials to higher market prices but this measure is hardly used in the German food and feed industry (figure 3). Just 11% of factories in the food industry and 3% of feed factories (which avoid GMOs) mentioned to take no additional efforts due to the existing GMO legislation.

Compliance with legal traceability requirements of GMOs

Legal traceability and labelling requirements were extended when Regulation (EC) No 1829/2003 and 1830/2003 went into force in 2004. Before implementing those Regulations there was no legal labelling obligation of GM feeds in the EU. Additionally GMO labelling changed from the system of GMO detection to the system of GMO application under these regulations. Before 2004 labelling of GMOs in foods and feeds was required if transgene DNA or proteins were analytically detectable in foods and feeds. Now labelling is

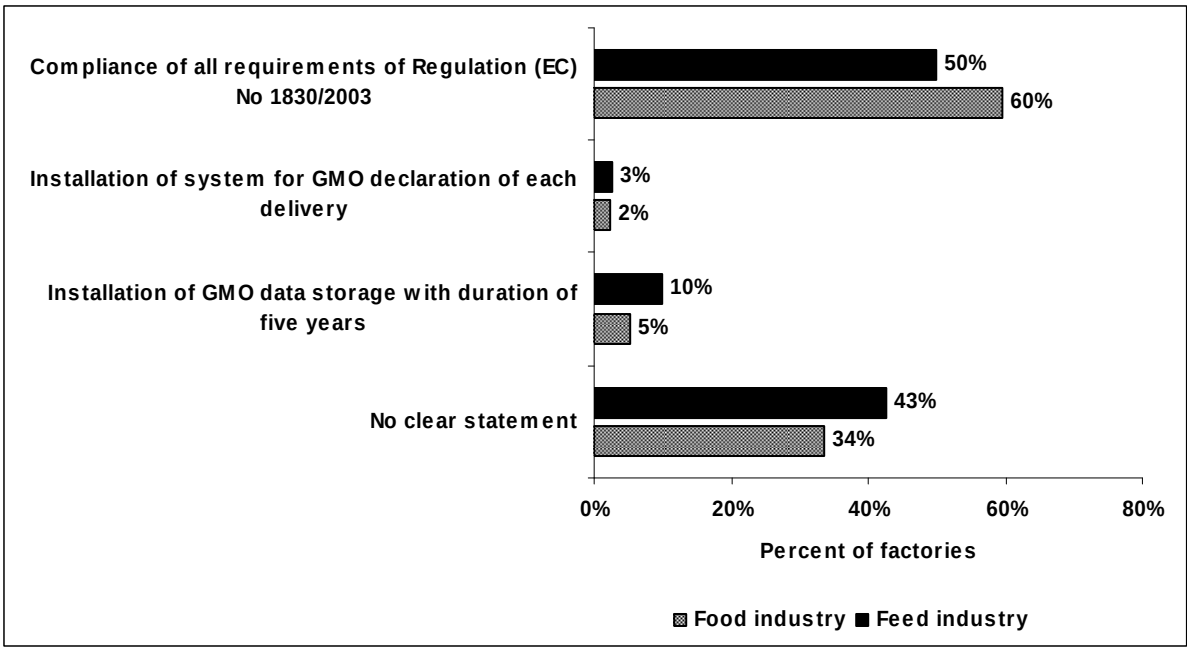
required if foods and feeds contain or consists of GMOs. This change leads to the consequence, that analytical GMO testing is no more suitable as sole detection method of GMOs with labelling obligation, because in some highly processed foods and feeds GMOs are not any more analytically detectable. Closing this gap Regulation (EC) No 1829/2003 and 1830/2003 require specific traceability measures for GMOs based on data documentation along the supply chain. In this context Regulation (EC) No 1830/2003 requires that “at the first stage of the placing on the market of a product consisting of or containing GMOs, bulk quantities, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

(a) that it contain or consist of GMOs

(b) the unique identifier(s) assigned to those GMOs in accordance with Art. 8”.

This identifier is a numerical or alpha-numerical code which is used to identify the GMO and to provide specific information about this GMO. Furthermore, operators have to provide systems of data documentation and standardised processes where those information can be saved. This data documentation system shall facilitate that each operator can be identified which was involved in trading transactions of GMOs during a time-frame of five years. In this context it is to mention that products consisting of or containing GMOs additionally have to fulfil general traceability requirements as it is demanded in Regulation (EC) No 178/2002 for all foods and feeds. Thus additional traceability requirements of GMOs are quite easy to integrate in existing data documentation systems.

Figure 4: How food and feed factories in Germany can comply the traceability requirements of Regulation (EC) No 1829/2003 and 1830/2003?



SOURCE: OWN INVESTIGATION

According to the survey 60% of the food producers mentioned to fulfil all traceability requirements of regulations (EC) No 1829/2003 and 1830/2003 although there is currently no use of GMOs in the German food industry and thus those GMO traceability requirements are not relevant for the companies. Additionally 50% of the feed factories mentioned to meet GMO traceability requirements. However, in case of the feed industry the situation significantly differs from those of the food industry since 64% of the feed factories mentioned to use GMOs and installing of GMO traceability systems is compulsory for those companies[1]. 34% of food and 43% of feed factories had no clear statement (figure 4) what shows the high level of uncertainty and lack of information in these industries.

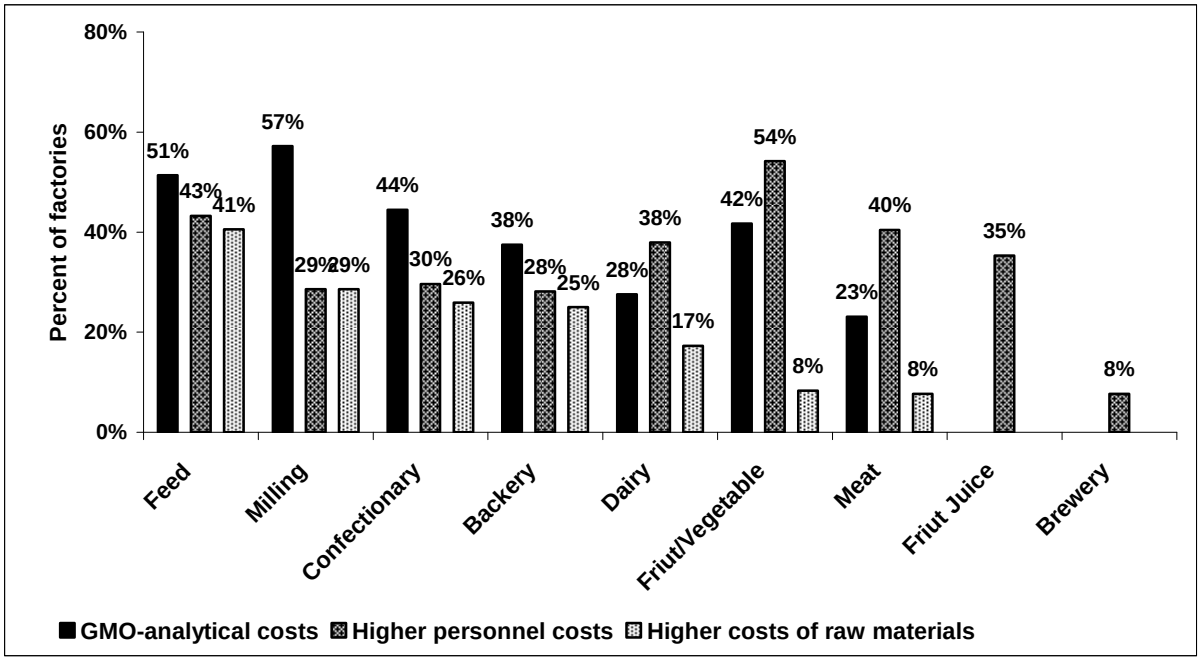
Economic impacts of labelling and traceability requirements

[1] The existing gap between the 64% of feed factories which use GMOs and the 50% of factories which have already installed traceability systems for GMOs can be interpreted as delays in implementing the existing EU regulations in the feed industry.

According to the results of our survey there are differing economic impacts of Regulations (EC) No 1829/2003 and 1830/2003 onto the German food and feed industry. Main costs arise throughout GMO analytics, additional personnel efforts and higher costs of GMO-free raw materials. Altogether the feed industry obtains the highest costs of avoiding GMO labelling under compliance of Regulations (EC) No 1829/2003 and 1830/2003. In feed industry additional costs of GMO free raw materials can reach 1.4% of the turnover, additional personnel costs can amount to 0.3% of the turnover and additional GMO analytic costs can rise up to 0.6% of the turnover. Regarding the food industry the milling-, confectionary-, bakery- and dairy factories are mostly affected of Regulations (EC) No 1829/2003 and 1830/2003. Good indication of GMO pressure on different food branches is given through higher costs of GMO-free raw materials since this indicates that used raw materials deriving from soybean, rapeseed, corn or cotton are replaced by raw material substitutes from other crops without GMO pressure or certified GMO-free raw materials with in general higher prices. According to our survey a factory of margarine and special fats obtained the highest additional costs of GMO free raw materials with about 0.4% of the turnover. A factory of confectionary products obtains highest additional personnel costs of around 0.2% of the turnover. A factory of soy products mentioned to have the highest additional costs due to GMO analytics of around 0.1% of its turnover. GMO analytic costs were most frequently mentioned by food factories: In average a frequency of about 39 times per year of GMO testing can be calculated for the German food industry. Regarding GMO analytics there are different strategies: Most factories transfer GMO analytics to labs and just big companies do their own GMO analytics. GMO tests are conducted testing specific ingredients or the final end products. Qualitative test regimes are cheaper than quantitative test regimes, some factories use both and others apply just one of the two options. The proportion

of factories of selected branches of the German food and feed industry which mentioned to have higher costs due to Regulations (EC) No 1829/2003 and 1830/2003 are shown in figure 5.

Figure 5: Proportion of factories which are affected by additional costs throughout regulations (EC) No 1829/2003 and 1830/2003



SOURCE: OWN INVESTIGATION

Conclusion

The food and feed industry in Germany is affected by the worldwide increasing use of GMOs and by the requirements of Regulations (EC) No 1829/2003 and 1830/2003 although German food factories try to avoid GMOs which would require labelling. Measures and costs of avoiding GMOs in German food and feed production depend on branches and raw material use. Additional cost of GMO free raw materials lead mainly in the feed and in some cases in the food industry to considerable higher costs in particular in such branches in which soybean, corn, rapeseed are main ingredients or derived products are used. So far it seems that applied measures to avoid GMOs in food production have been

sufficient in resent years. According to results of governmental control agencies in Bavaria and Baden-Württemberg labelling requirements of Regulations (EC) No 1829/2003 and 1830/2003 have been fulfilled in the year 2004 since only in few cases there was GMO admixture detected in food products, and if so this was mostly under compliance of legal thresholds without labelling obligations (TRANSGEN, 2005D). Main traceability requirements of Regulation (EC) No 1830/2003 are the forwarding of the unique identifier(s) assigned to GMOs of each delivery and storing such information five years in order to identify each partner of GMO transactions. Efforts to integrate those requirements are not too high because general traceability is already requested throughout Regulation (EC) No 178/2002 and thus traceability systems and data documentation is already organized in the German food industry.

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