


Economic impacts of labelling thresholds for the adventitious presence of genetically engineered organisms in conventional and organic seeds

SEED PURITY: COSTS, ADVANTAGES AND RISK
MANAGEMENT FOR MARKETS AVOIDING
GENETICALLY ENGINEERED PLANTS

Christoph Then / Matthias Stolze

PUBLISHED AND EDITED BY





Economic impacts of labelling thresholds for the adventitious presence of genetically engineered organisms in conventional and organic seeds

SEED PURITY: COSTS, ADVANTAGES AND RISK
MANAGEMENT FOR MARKETS AVOIDING
GENETICALLY ENGINEERED PLANTS

Christoph Then / Matthias Stolze



Edited and published by
IFOAM EU GROUP
Rue du Commerce 124 - BE - 1000 Brussels

Phone: +32 2280 1223

E-mail: info@ifoam-eu.org

Webpage: www.ifoam-eu.org

Brussels, December 2009

Authors:

Christoph Then, Testbiotech  Matthias Stolze, Fib 

Editor:

Marco Schlüter, Antje Kölling

Language editing:

Louisa Winkler

Production and Layout:

Production Sud

Printed on Cyclus print paper

Download of electronic version from: www.ifoam-eu.org

All online sources as referred to in the footnotes without further comment have been checked on 21st December 2009 latest.

This study is co-financed by the European Community, Directorate-General for the Environment.

The sole responsibility for the communication/publication lies with the author.

The Commission is not responsible for any use that may be made of the information contained herein.



TABLE OF CONTENTS I

Summary.....	4
1. INTRODUCTION	7
2. THE CASE OF FLAX CDC TRIFFID AS A RECENT EXAMPLE OF SEED CONTAMINATION	8
• Background and History.....	8
• Impact on markets.....	9
• Risk related aspects.....	10
• Some lessons learnt from the Triffid case.....	11
3. GENERAL ISSUES RELATED TO SEED CONTAMINATION	12
<i>Overview of seed contamination cases</i>	12
<i>Seed contamination can be self-perpetuating</i>	13
<i>Seed contaminations still occur after de-registration</i>	14
<i>Seed contamination affects markets at large scale</i>	15
<i>Technical issues related to seed purity</i>	16
<i>Measures to achieve seed purity</i>	17
<i>Achieving seed purity at a level of 'zero' threshold</i>	17
4. COSTS OF SEED PURITY	19
<i>Data for seed production in Europe</i>	19
<i>Maize seed</i>	19
<i>Sugar beet seed</i>	20
<i>Oilseed rape (OSR)</i>	21
<i>Soybean seed</i>	21
<i>Costs of co-existence in seed production</i>	21
5. THE SITUATION IN DOWNSTREAM MARKETS	25
<i>The regulatory framework in the EU</i>	25
<i>Some data on costs in agriculture and food production</i>	27
<i>Costs of segregation in the German market</i>	28
6. SPECIFIC CASE STUDIES	30
<i>Case 1: Milling company (Germany)</i>	30
<i>Case 2: Organic tofu processor (Germany)</i>	32
<i>Case 3: Milling company (France)</i>	34
<i>Case 4: Organic food company (Germany)</i>	36
<i>Case 5: Organic soy food processor (France)</i>	38
<i>Case 6: Food processor for soya products (France)</i>	40
7. IMPACT OF DIFFERENT LABELLING THRESHOLDS ON FARM PRODUCTION	43
8. AVOIDING CONTAMINATIONS THROUGHOUT THE FOOD CHAIN	49
9. FURTHER ASPECTS OF RISK MANAGEMENT	53
10. CONCLUSIONS	56
11. RECOMMENDATIONS	58
Definitions and abbreviations.....	59
References.....	60




Summary

Within the EU, the option of establishing labelling thresholds for the adventitious presence (AP) of genetically engineered (GE) organisms in conventional and organic seed has been under discussion for several years. It can be expected that the Commission will come up with a legal proposal for a labelling regime between 2010 and 2014.

The level of the labelling threshold will have profound impacts on the future of farming with respect to the possibility of co-existence and consumer choice: co-existence costs for farmers and the entire food chain will be influenced by the level of seed purity. A labelling threshold above 'zero' would allow contamination with GE organisms to become permanently entrenched at the seed level; this would threaten existing EU food markets that rely on segregation, traceability and transparency. It would increase costs for maintaining co-existence and also bring about financial losses for farms and processors. Consumer choice will be narrowed, and in some market segments even completely eliminated. To some extent the tasks of the risk manager will be impacted as well.

To permit permanent admixtures of genetically engineered (GE) seeds without labelling is to integrate a degree of contamination into the food chain on a permanent basis. Without doubt, this would impact farms, grain elevators, processors and food producers, already under economic pressure in complying with legal requirements and demand-driven quality standards. Up to levels of 0.9 percent, the adventitious and technically unavoidable presence of GE components in food and feed is exempt from labelling requirements in European legislation; this provides a safety margin for non-GE food production. To make sure that the end product stays below this threshold, food industries have established thresholds of between 0.1 and 0.5 percent for adventitious and technically unavoidable presence of GE components in raw products. Farmers therefore have to work within a margin that lies between the labelling threshold in seed and the thresholds set by the industry at 0.1-0.5 percent. However, any contamination of seed can become a major problem for the downstream food and feed chain, making it difficult to keep levels of GE components below 0.9 percent in the end product. The possibility arises that sensitive food markets might collapse as a result, rendering farmers unable to sell their products.

This study presents data enriched by detailed case studies affording an overview of the costs associated with avoiding GE components in food production. It was found that the current safety margin of 0.9 percent for the labelling of adventitious or technically unavoidable presence of GE components in feed and food requires significant investments and high annual costs for food production in Europe. Total yearly co-existence costs



for the EU food and feed processors introduced in the case studies range from about €880,000 to €50,000. Thresholds of over 0.1 percent for adventitious presence of GE seed in non-GE batches are likely to increase these costs and the associated strains on farmers, food and feed processors, traders and retailers. With regard to establishing effective co-existence measures that enable segregation in European food production, seed production plays a pivotal role. Seed contamination can be self-perpetuating, affect markets on a large scale, and can occur even after a GE crop is de-registered. Seed contaminations not only show patterns of broad spatial distribution but also of persistence over long periods of time. On the basis of these economic and technical analyses this study recommends a low labelling ('zero') threshold for adventitious presence (AP) of authorised GE seed in non-GE seed. For the purpose of this report a 'zero' threshold is defined as a thresholds below 0,1 percent in accordance with the Austrian Seed Law (Saatgut-Gentechnik Verordnung, 2001).

There is strong evidence that seed purity is of fundamental importance for co-existence and only low (zero) labelling thresholds for seed enable farmers and processors to obtain at reasonable costs end products that do not have to be labelled as GE. The feasibility of complying with a low ('zero') labelling threshold for AP of authorised GE seed in non-GE seed varies depending on conditions, and should be sensitively assessed from all perspectives. There are, however, no insurmountable hurdles in evidence. To the contrary, compared to other sectors such as agriculture and food production, seed production has several characteristics which are advantageous for effective implementation of specific co-existence measures:

- In breeding and production of seed, specific measures against comingling with other conventional varieties are already established that can be adapted and developed.
- Areas used for seed production (that can be subjected to specific co-existence measures) are small compared to areas for agricultural production and are concentrated in certain regions. The amount of seed that produced (and needs to be controlled) is small in the context of millions of tons of agricultural commodities and the vast range of food products on the market.
- Europe has the potential to be largely self sufficient in the production of the most sensitive seeds such as maize. Thus, EU measures to maintain seed purity can benefit EU farmers and EU food producers on broad scale.



Due to the fact that the area used for seed production is many times smaller than the overall agricultural area, it may be assumed that overall segregation costs for the whole food production chain can be kept smaller if the strictest measures are applied to seed production, where they are comparatively low-cost.

From data available it can be concluded that there are no general obstacles to implementation of specific measures protecting seed purity for crops such as maize in Europe. A different view would have to be taken regarding crop species such as oilseed rape, which are able to outcross and backcross over large distances and show a long period of (viable) seed dormancy.

Existing data show that costs for maintaining seed purity mainly emerge in the seed propagation phase, especially in regions where GE and non-GE crops are grown in close proximity. But despite extensive publications on co-existence, so far no targeted studies are available identifying exact costs and measures necessary to establish seed purity at low ('zero') thresholds for labelling of AP of authorised GE seeds. Such detailed and targeted studies would be a basic prerequisite for the EU decision making process.

It is not yet possible to answer all relevant questions on the presence of GE seed in non-GE seed, but this study has identified some of the most crucial points for further discussion and investigation. Among these is the possible establishment of legally binding rules based on the 'Polluter Pays' principle in the seed market, to apply to companies that introduce GE components into the agricultural sector and food chain.

Seed protection mechanisms could be accompanied by financial support from the EU budget. Support for seed purity can be justified since this is a risk management issue for reasons beyond the purely economic: in the case of new scientific evidence showing unexpected threats to human health and/or the environment, the EU risk manager must establish mechanisms that allow for a withdrawal of GE seeds within a reasonable period of time. Also, traceability and monitoring requirements for GE plants as outlined in EU regulations depend upon seed purity.

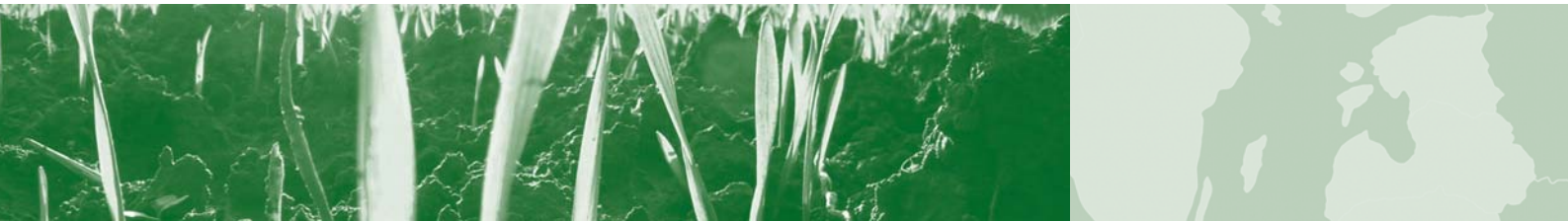
1. INTRODUCTION

The issue of seed purity and thresholds for labelling of adventitious presence (AP) of authorised genetically engineered (GE) seeds has been the subject of intense discussion within the European Union for the past several years. Several actors have proposed the introduction of labelling thresholds as a practical measure; proposed thresholds have ranged between 0.1 percent and 0.5 percent (see for example Scientific Committee on Plants, 2001).

This study was undertaken to explore possible impacts of these thresholds. Various aspects of farming, food production and seed production were investigated, including.

- mechanisms and patterns of seed contamination
- economic data for seed production and measures for seed purity
- economic data about downstream production impacted by seed purity, including case studies (food and feed processors in Germany and France)
- analyses of benefits of seed purity for food production and for co-existence in agricultural production
- risk management issues beyond the purely economic

Scientific publications were analysed as well as documents released by the authorities. To examine the downstream costs of certain AP thresholds for authorised GE seeds, a questionnaire was developed and a series of interviews with six food and feed processors conducted. Data were compiled on costs for testing, storage, cleaning, education and training, as well as costs for dealing with contamination outbreaks. Further data from the Scientific Committee on Plants 2001 were used to calculate the impact of different thresholds on farming practice.



2. THE CASE OF FLAX CDC TRIFFID AS A RECENT EXAMPLE OF SEED CONTAMINATION

Unlabelled seed contamination may have lasting impacts and cause damage to the food industry long after the GE plant concerned has been withdrawn, as is shown by the recent example of Flax CDC Triffid. In September 2009, GE plants believed to have been exterminated returned to life: herbicide-tolerant Flax CDC-FLØØ1-2 (FP967), more commonly known as Triffid, was found in European markets. The Flax Council of Canada made the decision in 2001 to destroy the entire seed stock of Triffid flax in what it described as "one of the most sophisticated and extensive risk management plans ever adopted". Nevertheless, the GE crop later reappeared in food products in several EU countries and later on in regions outside the EU, as was discovered to the shock of European markets in 2009. The news agency Reuters reported the case on October 5, 2009:¹

"The flax-contamination reports include seven from Germany, two from France and one each from Sweden and the United Kingdom. They state that buyers distributed the contaminated product to 24 more countries -- Belgium, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Luxembourg, the Netherlands, Poland, Spain, Italy, Austria, Portugal and Romania in the European Union -- as well as Croatia, Iceland, South Korea, Norway, Singapore, Sri Lanka, Thailand, Mauritius and Switzerland outside the EU".

The Triffid case exemplifies some general problems associated with seed contamination:

- seed contaminations can be self-perpetuating
- seed contaminations can result in high costs for risk management measures
- seed contaminations can result in high costs for downstream operators in the market such as farmers, processors and food producers
- seed contaminations create not only economic but also environmental and human health risks.

• Background and History

The Triffid plants belonged to the very first generation of GE plants brought to market. They were developed in 1988, received market authorisation in Canada in 1996, and were approved in the USA in 1998/1999. Flax Triffid was propagated by seed producers in Canada, but market authorisation was withdrawn in 2001, before large scale commercial growing took place. This was at the request of industry practitioners concerned about the loss of markets for Canadian flax. Measures were taken immediately to destroy the seed stock:

¹ "Europe finds GMO in 11 Canada flax shipments", Reuters, published Mon Oct 5, 2009
<http://www.reuters.com/articlePrint?articleId=USN0537374020091005>

"The Flax Council of Canada, in one of the most sophisticated and extensive risk management plans ever adopted, acquired all of the certified seed produced and had it destroyed or crushed domestically"
(Flax Council of Canada, 2009).

Despite these efforts, CDC Triffid was found in European shipments of flax seed from Canada and in a large number of food products such as baked goods and cereals in 2009. The number of countries affected gradually rose, hitting 28 by early October² and 34 by the end of the month³.

The entry point of the contamination is not yet known exactly. Although Triffid was approved for market, it was never grown commercially in Canada. Seed producers had propagated it, but all seeds were supposed to have been destroyed in 2001. Considering the long time period between 2001 and 2009, it is likely that the source of contamination was viable seeds, which could have been reproduced, propagated and brought to the fields inadvertently over several years. The details known so far have not been sufficient to implicate any specific regions or seed lots. The only significant differentiation is that between organic products, which showed less or no contamination, and conventional products.

• Impact on markets

The CDC Triffid case had negative economic impacts on at least three main constituencies:

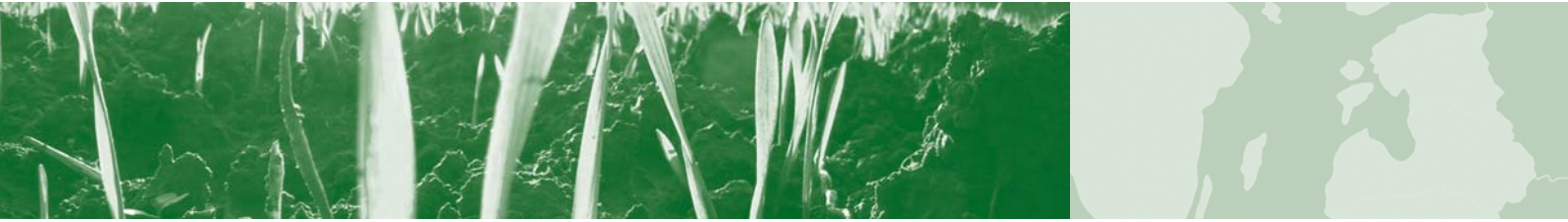
1. The European food industry. Several European food producers started to test their products more thoroughly and to recall products from the stores. Most affected were bakery and cereal products. Official figures are not yet available for the damage caused to the European food industry, but a large number of food products were affected⁴.
2. International trading companies and Canadian exporters. Canada is the world's biggest producer of flax, and around 70 percent of its 900,000 ton annual output is exported to European markets. Since exporters can only sell Canadian flax into Europe provided they guarantee the shipment is free from GE components, the contamination incident has in effect closed the market to them. European market demand for Canadian flax collapsed, and analysts now regard as the only possible recourse a switch to other markets such as the US (where CDC Triffid is still authorised) or China⁵.

² see previous footnote

³ "Attack of the Triffids has flax farmers baffled", The Globe and the Mail, Published 27 October 2009 by Martin Mittelstaedt http://v1.theglobeandmail.com/servlet/story/RTGAM.20091027.escenic_1340838/BNStory/National/

⁴ "Illegalen Gen-Leinsamen in Brötchen und Müsli", Greenpeace Germany, published 11 September 2009 http://www.greenpeace.de/themen/gentechnik/nachrichten/artikel/greenpeace_weist_nach_illegaler_gen_leinsamen_in_broetchen_und_muesli-1/

⁵ "GM issue keeps flax bids under pressure" Manitoba Co-operator, published 16 October 2009 by Phil Franz-Warkentin <http://www.manitobacooperator.ca/issues/ISarticle.asp?aid=1000344285&issue=10162009&pc=FBC>



3. Flax-producing farmers. The Manitoba Co-operator reported on the 16th of October 2009 that Canadian farmers were facing severe difficulties finding buyers for their harvest:

"[M]any of the elevators don't want to see a lot of flax, due to the lack of movement to Europe, and are only offering low prices to keep the commodity from coming in. For the most part, I wouldn't think that too many of the bigger companies want to see much flax come in right now," said [Paul] Martens [co-ordinator of operations with Prairie Flax Products at Portage la Prairie, Man].

*"We have too much product and not enough places to put it," added Mike Jubinville of ProFarmer Canada."*⁶

No wonder that the price was falling: just prior to the crisis, Canadian flax had been selling for around 10-11 Canadian dollars (\$C) per bushel; in October 2009, farmers could only expect between \$C 6 and 8 per bushel, if they were lucky enough to sell their flax at all.⁷ On the 27th October, Canadian newspaper The Globe and Mail reported that Triffid was threatening the entire Canadian flaxseed industry, worth \$320 million a year.⁸

• Risk related aspects


The technical construction of the CDC Triffid flaxseed genotype is outdated, partly deficient and associated with some uncertainties related to health risks. The gene construct conferring tolerance against the Sulfonylurea herbicides (the ALS gene) is derived from a plant called *Arabidopsis thaliana*. There are four additional genes inserted from bacteria, three of which are antibiotic resistance marker genes (ARMGs). Problematically, the European Food Safety Authority has identified some of the antibiotics concerned as essential for human health protection, meaning that the development of resistant bacteria would have serious medical implications (EFSA2004 and 2009). Moreover, European legislation requires that antibiotic resistance genes should be avoided or phased out completely (EU Directive 2001/18). The CDC Triffid genome also contains a further gene sequence coding for nopaline synthesis, which was integrated as a marker gene (similar to the ARMGs) to allow identification of plants which are successfully transformed. This technical element was already outdated in 1998 when the plant was submitted to the US authorities for approval. Alan McHughen, the scientist leading the team that developed CDC Triffid, noted in his application document:

"This [gene] fragment results in production of nopaline by the successfully transformed plant cell. Nopaline is easily detected using a simple test. However it is obsolete now, as it is weak and many ordinary plant species (eg. soybean) produce nopaline" (McHughen, 1998).

⁶ see previous footnote

⁷ see previous footnote and "Prairie flax bids fall as GM concerns continue", Manitoba Co-operator, published 29 September 2009 <http://www.manitobacooperator.ca/issues/ISarticle.asp?aid=1000342567&issue=09292009&pc=FBC>

⁸ "Attack of the Triffids has flax farmers baffled", The Globe and the Mail, Published 27 October 2009 by Martin Mittelstaedt, http://v1.theglobeandmail.com/servlet/story/RTGAM.20091027.esenic_1340838/BNStory/National/



According to analyses performed by McHughen's team, the Triffid plants contained not just one but two copies of the complete gene construct plus a third which became fragmented (McHughen, 1998). It was not known then, and nor is it now, at exactly what locus on the chromosome this additional genetic information is integrated into the genome of the plants, or if it affects the activities of other genes. It is, however, confirmed that three of the additional genes show biological activity: the ALS gene, one of the ARMGs and the nopaline synthase gene.

In conclusion, CDC Triffid flaxseed can be described as a product that is technologically outdated. With several substantial uncertainties existing related to the technical quality of this product, its technical features also raise some specific safety concerns.

Not only does the product itself suffer from being technologically outdated, but also the methods used for its risk assessment are not up to modern standards. The risk assessment of CDC Triffid was conducted about 20 years ago, before the first market application in Canada. Since that time, more detailed methods have been developed for investigation of unexpected changes in the genome, the epigenome and metabolome. Furthermore, no feeding studies were performed on the plants. The concentration of the most significant plant compounds (highly toxic cyanogenic glycosides) was not investigated as it should have been, under a range of differing environmental conditions that might influence their production.

Risk management in the EU aims to enforce the highest available standards by requiring evaluation of relevant data from authorised GE crops every ten years. CDC Triffid, however, was never authorised in the EU, and furthermore was officially taken off the Canadian market in 2001; as a result, the newest data available on the plant were generated about 20 years ago, with no reassessment undertaken since.

• Some lessons learnt from the Triffid case

The case of CDC Triffid is highly relevant for the issue of seed purity and the discussion of thresholds, having demonstrated some crucial facts:

- Even if seed is only contaminated in very small quantity, the contamination can persist undetected over many years.
- Even very slight contamination of seed can affect international trade and the food market on large scale.
- The withdrawal of a GE organism after annulment of its authorisation becomes extremely complicated for the risk manager, as the GE trait quickly contaminates conventional seed.



3. GENERAL ISSUES RELATED TO SEED CONTAMINATION

Documented cases of contamination by GE seeds are numerous. In general, cases concerning unauthorised seeds are different from those concerning authorised seeds, having a different legal and economic impact on markets; therefore, they are comparable only to a limited extent. This study presents some well-documented cases of contamination with unauthorised seeds, cases which can be used to exemplify patterns of distribution, general impact, possible entry points for contamination and mechanisms of perpetuation. Such cases are useful for anticipating the possible impacts of contamination after market withdrawal of GE seed.

Overview of seed contamination cases


Numerous cases of contamination with unauthorised GE seeds have been reported during the last decade. Many of them are listed in the online GM Contamination Register.⁹ Officials at the U.S. Government Accountability Office (GAO) also published a list of relevant cases in 2008 which is used herein to give a short and by no means comprehensive overview (Table 1).

Table 1: Some cases of contamination with genetically engineered plants from 2000-2008
(Source: GAO, 2008)

Year	Product	Crop	Trait	Cause	Detection
2000	StarLink	Corn	Insect resistance and herbicide tolerance	Cross-pollination, commingling of corn after harvest	Third-party testing
2002	Prodigene	Corn	Pharmaceutical protein	Cross-pollination and uncontrolled volunteers ^a	USDA inspection
2004	Syngenta Bt10	Corn	Insect resistance	Misidentified seed	Third-party testing
2006	Liberty Link Rice 601	Rice	Herbicide tolerance	Not determined	Third-party testing
2006	Liberty Link Rice 604	Rice	Herbicide tolerance	Not determined	Third-party testing
2008	Event 32	Corn	Insect resistance	Under investigation	Developer testing

Source: GAO analysis of USDA and EPA data.

⁹ GM Contamination Register, GeneWatch UK and Greenpeace International
<http://www.gmcontaminationregister.org>



The British Government's Central Science Laboratory¹⁰ investigated the current status of seed contamination with GE seeds in European Union member states (2007). It found a total of 280 incidents involving authorised GE seeds had occurred between 2001 and 2006, plus 43 incidents involving unauthorised seeds. Most of the incidents reported involved maize; a small number involved oilseed rape. The authors calculated that overall, 3.2 percent of tests detected the presence of GE components. Of these, 33.3 percent detected 0.1 percent presence, 37.5 percent detected between 0.1 percent and 0.3 percent presence, and 6.25 percent detected over 0.9 percent presence. Since the plant species requiring testing, the protocols for testing, the number of samples taken per seed lot and the level of tolerance for adventitious presence of GE seeds are not standardised throughout the EU, the figures leave some uncertainties.

In the following sections, three characteristics of seed contamination are discussed which are of relevance to protection of seed purity. Subsequently, technical issues relating to protocols for testing and plant biology will be addressed.

Seed contamination can be self-perpetuating

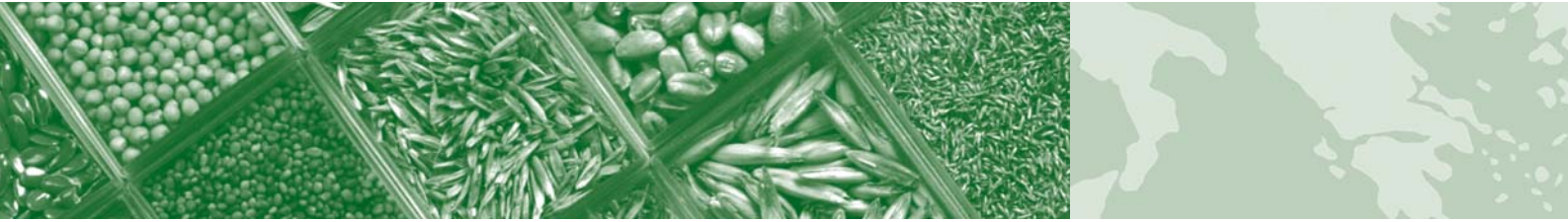
As shown in Table 1 (GAO, 2008), viable seeds played a role in several contamination cases, for example that of Bt10. Because of insufficient testing, the spread of seeds containing Bt10 is thought to have continued undetected over the course of several years. Maize is a cross-pollinating species highly vulnerable to contamination, while soy and wheat, for example, are self-pollinating with much lower frequency of gene flow. Once established, contaminated seeds can survive in the production and propagation chain, perpetuating contamination over several years without being noticed.

In rice contamination, too, seeds are likely to be the entry point for contaminations. In the case of LL Rice 601 from Bayer, field trials took place before 2002, but the first contamination was reported only in 2006; this makes it likely that viable seeds were the source of (perpetuated) contamination. Even seeds of the BASF variety (Clearfield 131) were contaminated with LL Rice 604.¹¹ Another case of rice contamination concerns Bt63, a GE rice from China which was found on the European market for the first time in 2006 and is still appearing in European food analyses in 2009, despite not having been authorised in China or elsewhere.¹² Lu and Yang (2009) describe specific mechanisms for crossings between seeds of wild and cultivated rice

¹⁰ Now called the Food and Environment Research Agency (as of April 2009)

¹¹ GM contamination register, GeneWatch UK and Greenpeace International
<http://www.gmcontaminationregister.org>

¹² see footnote 11



which can help to explain why for rice in particular, contamination can become a problem that perpetuates over many years.

In Germany, a case of oilseed rape seed contamination was reported in 2007. The German plant breeding company Deutsche Saatveredelung discovered contamination by GE plants resistant to the herbicide Glufosinate. It is likely that the seeds had come from field trials performed by the company several years earlier (Then and Lorch, 2009). Seed dormancy, drift of pollen and wild species (that can cross with cultivars) all complicate the preservation of crop genotype purity, especially once cultivation reaches a larger scale. In the Deutsche Saatveredelung case, the farmers concerned were requested not to sow oilseed rape within a specified 1500 ha area for several years, to enable destruction of the volunteer plants.¹³


This short overview shows that seeds can contribute to contaminations which self-perpetuate over long periods of time, through mechanisms such as undetected propagation, crossing and back-crossing with wild species, and seed dormancy. Such contamination events can have drastic consequences for producers and markets.

Seed contaminations still occur after de-registration

As has been described, contamination with GE seeds can self-perpetuate and persist in cultivated populations over long periods of time, even where the seed population from which they originated is withdrawn from the market. This is to say that contamination by an authorised GE seed might become contamination by an unauthorised GE seed over longer periods of time.

European Union legislation requires reassessment of authorised GE organisms every ten years, on the basis of which their approved status can potentially be lost. Since GE plants are technical products that might undergo unforeseen developments or demonstrate unexpected deficiencies in their technological qualities, there has to be an effective and efficient system for withdrawing them from the market completely. In light of the understanding we have of mechanisms that can contribute to the persistence of contaminants in plant cultivars, the necessity for viable withdrawal is a strong argument for maintaining seed purity at a 'zero' tolerance (further details can be found under 'definitions') for AP of GE seed. Integral contaminations

¹³ "Biotech traces in German Rapeseed Seeds" USDA Foreign Agricultural Service, Published 7 September 2007 by US Embassy Berlin <http://www.gmcontaminationregister.org/index.php?binobj=file&cmd=passthru&oid=78>



established by labelling thresholds higher than 'zero' in seed production might render it impossible to withdraw GE plants from the market effectively and efficiently (within reasonable period of time and under practical economic conditions). It is a technical possibility that we could see residues of de-authorized GE seeds accumulating in seed stocks, creating new combinations of engineered genes which were never tested or authorised.

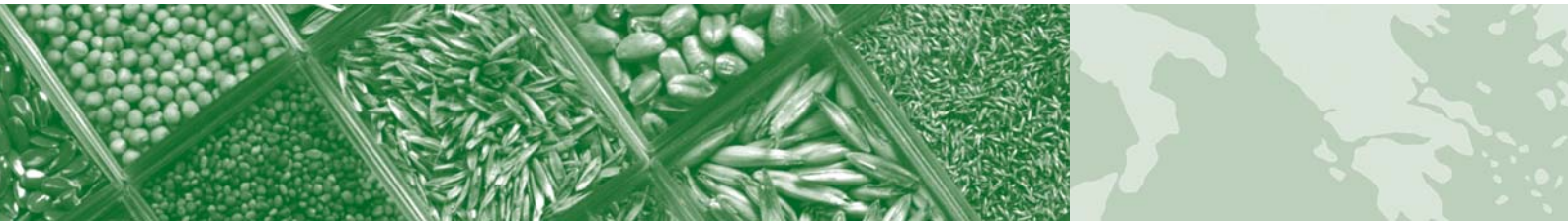
Several real-life cases where a GE product was discontinued by a company or de-authorized already exist. Amongst these are FlavrSavr tomatoes, Zeneca's tomato paste, NewLeaf potatoes, Triffid Flax, StarLink maize and Bt 176 maize. The reasons for their withdrawal or official de-registration are various: consumer rejection, quality problems, potential allergenic risks or potential risks to non-target organisms (see discussion below).

As the case of CDC Triffid flaxseed shows, contamination can be discovered many years after the official de-registration, even though the plant was never grown commercially in Canada. In 2001, about 40 farmers were propagating 200,000 bushels of seed for future use, but this was all destroyed when Triffid was taken off the market that year. The destruction process was carefully controlled by the authorities, who waited for written confirmation of the complete destruction of seeds before finalising official de-registration.

By introducing thresholds of 0.3 percent or 0.5 percent for labelling of the adventitious or technically unavoidable presence of GE seeds in conventional seed, the European Commission would allow the unintentional low-level propagation of GE traits in cultivar populations. In the Triffid case, only 40 farmers and 200,000 bushels of seed created a problem of international dimensions; in consideration of this, we can expect that 0.3 percent or 0.5 percent labelling thresholds would lead to completely uncontrollable spread of GE components, even after the parent seeds are removed from the market.

Seed contamination affects markets at large scale

It is known that relatively small amounts of seed generate a plant population which can extend over a very large area, and thus that the distribution of contaminated seeds can broaden rapidly to significant scale. Figures provided by Ceddia and Cerezo (2008) allow us to compare areas of agricultural production in the EU with areas used for seed production (see Table 2). It is interesting to note that the areas needed for seed



production are relatively small compared to the much larger area of agricultural fields used for the production of millions of tons of commodities. This fact is significant in two respects:

- If non-zero thresholds are allowed for AP of GE seeds, the distribution of the contaminated seeds can easily extend over large areas of the EU, massively affecting agricultural and food production.
- If measures are taken to maintain seed purity, large parts of the agriculture and food production sectors (i.e. those that aim for products free from GE organisms) will benefit.

Table 2: Comparison of areas needed for seed production with areas used for crop production in the EU (source: Ceddia and Cerezo, 2008).

	Area of seed production	Area of agricultural production
Soy	11,000 ha	0.28 million ha
Maize	67,000 ha - 86,000 ha	5.8 - 6.5 million ha
Sugar Beet	5,200 - 8,300 ha	2.2 million ha
Oilseed Rape	8,600 ha	4.7 million ha

It is evident that even slight contamination of seed can have a major impact on farming and food production. Seed contamination made permanent by non-zero thresholds can spread to far reaches of the global market within a relatively short period of time.

Technical issues related to seed purity

Two technical issues will be discussed in the paragraphs below: what measures are necessary to achieve seed purity, and what measures will subsequently maintain it.

Measures to achieve seed purity

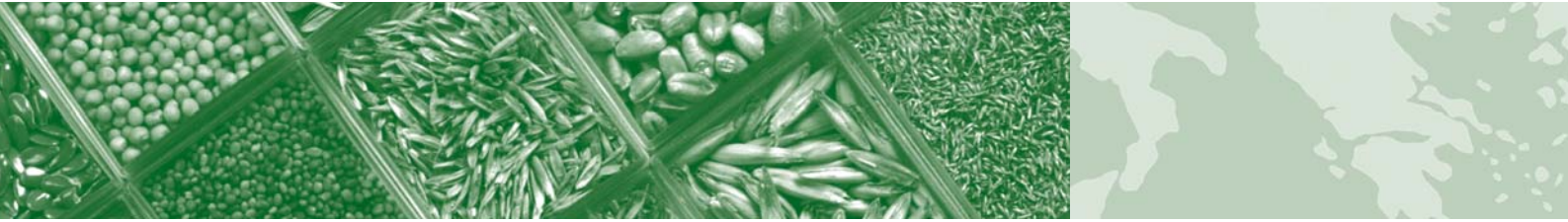
Seed purity is a concern in all seed production, not limited to avoidance of GE components. Companies must implement strict control systems to make sure that their varieties do not get mixed with others. Thus, prevention of AP of GE seeds in non-GE seed can be at least partially achieved using the existing quality control framework. This is especially relevant for the initial phase of breeding where extremely high standards for seed purity have to be achieved. Since only smaller areas are necessary for this initial level of breeding and quality standards are already demanding, the prevention of AP can be achieved more easily at this stage than at later stages of seed production.

Propagation of seed requires larger areas than does initial breeding, though they are still small compared to areas required for crop production (see Table 2). In the case of maize, the EU's most suitable propagation areas are also the most suitable commercial production areas. In light of this, new strategies might be required for protection of seed purity, including such practices as clustering, regionally organized agriculture without GE plants, greater isolation distances, buffer zones, and changed cultivation methods. Appropriate strategies will depend on the species of plant; in general, AP is more difficult to control in cross-pollinating species such as maize, oilseed rape and sugar beet than in self-pollinating species like wheat and soy.

Achieving seed purity at a level of 'zero' threshold

Another relevant question is how seed purity or the compliance with certain thresholds can be maintained. The 2007 report of the UK's Central Science Laboratory found that test protocols of the various member state authorities are quite heterogeneous, such that results of monitoring plans are not always directly comparable: "The effectiveness of a control programme is not simply a function of the level of sampling and testing undertaken, but is described by a combination of the sources of uncertainty introduced by sampling (primary sample through to laboratory working sample), the number of samples taken, the limit of detection of analytical tests, [and] decisions taken with respect to labelling and enforcement (which currently varies across Member States)" (Central Science Laboratory, 2007).

There are several technical matters related to the setting of labelling thresholds in law. The two most important ones are the level at which presence of GE components can be detected, and the level at which their presence can be accurately calculated (quantified). In both of these matters, our technical capabilities



are evolving and improving constantly, which the law should also recognise. With today's laboratory practises, we can detect traces of GE components anywhere above a 0.01 percent limit, and quantify their presence anywhere above 0.1 percent. For variability of measurements a relative standard deviation below 50 percent is accepted, which means that the majority of results will range between 0.05 percent and 0.15 percent for test results at 0.1 percent (Community Reference Laboratory, 2008). In general it is safe to say that traces of GE seed are reliably detectable with current laboratory practise at 0.1 percent presence or above. The confidence level will be dependent on size of samples and number of controls.

With respect to EU-wide harmonisation of seed purity standards, the choice of test protocol can be decisive and will have impact on detection limits, ability to quantify results, and confidence level. Since a level of 100 percent seed purity is by definition unachievable, the question of how to define purity or 'zero' tolerance in a technical and practical sense is crucial.

Austrian authorities have successfully implemented a sub-0.1 percent threshold. The Austrian seed law (Saatgut-Gentechnik Verordnung, 2001) requires seed purity at the detection limit (about 0.01 percent) for first controls but then uses the technical level for quantification (0.1 percent) for all follow-up controls. Thus, there is a high probability of securing seed purity and 'zero' tolerance. This shows that in practical terms, 'zero' tolerance in seeds must be defined according to constraints set by our technical capabilities. We also observe, however, that control at the limit of technical capabilities can be effectively enforced (Leonhardt et al, 2009).

These technical aspects of testing are set aside in the following chapters. In some paragraphs the term "low ('zero') threshold" is used; this is with the awareness that technical limitations mean it is impossible to achieve 100 percent seed purity. The term refers, therefore, to the maximum seed purity that can be guaranteed within technical limits by effective controls.

4. COSTS OF SEED PURITY

Given the importance of seed production for all later stages of farming and food production, safeguarding seed purity under current and future conditions is a concern of the highest priority. Costs and opportunities of establishing seed purity must be properly evaluated, and regulations adopted accordingly. This section presents some basic data to elaborate on the costs and benefits of ensuring seed purity and an attempt to accurately calculate the costs of achieving and maintaining seed purity at a number of thresholds under a range of regional conditions.

Analysis is based on seed production data for soybean, maize, sugar beet, oilseed rape and others, compiled for a study of the structure and volume of the European market for certified seed (Ceddia and Cerezo, 2008); and on cost analyses on establishment of seed purity by co-existence measures for maize and other crops (Messéan et al., 2006; Kalaitzandonakes and Magnier, 2004).

Data for seed production in Europe

According to Ceddia and Cerezo (2008), Europe (including Russia and other non-EU 27 countries) was the largest market for commercial seeds in 2005 (around 32 percent of the total world market), followed by the USA (around 21 percent) and Asia (around 17 percent). The most important segment of the seed sector is cereal seeds (around 36 percent), followed by horticultural seeds (21 percent) and oilseeds (14 percent).

The EU is a net exporter of seeds. From 2001 to 2005 seed imports increased from US\$ 450 million to almost US\$ 580 million, and seed exports increased from US\$ 421 million to US\$ 876 million. The increase in the EU's trade volume was mainly due to an increase in shipments of vegetable seeds. US seed exports consist predominantly of vegetable seeds, oilseeds, and flower and tree seeds to the EU.

Maize seed

Ceddia and Cerezo (2008) identified the main EU producers of maize seed as France and Hungary, with France cultivating between 42,000 and 56,000 ha annually, producing outputs of between 142,000 and 160,000 tons during the period 2000 to 2005. Seed production mainly occurs in the south west, parts of central France and parts of western France. There is no regional segregation between seed and grain maize



production in France, but cultivation of GE maize has been outlawed in recent years (as of 2008). A significant proportion of France's maize output is exported (51 to 68 percent of domestic between 2000 and 2005). The main destinations for French maize seed are Germany, Italy and Spain. France also imports seed (around 47,000 tons in 2004), mainly from Hungary (13,000 tons in 2004), the USA (11,000 tons in 2004) and Chile (around 9,000 tons in 2004). However, most of the imports originating from the USA are of seed produced in Chile, which has a significant role in worldwide seed production for GE maize.

In Hungary, the area for maize seed production ranged between 25,000 and 30,000 ha during the period 2000 to 2005. Seed is mainly grown in the great Hungarian plains in the southern and eastern parts of the country. Most of the Hungarian maize seed output is exported (around 40,000 tons each year, equivalent to 60 percent of domestic production), its main destinations being the Netherlands, France, Germany and Italy. Hungarian seed imports are low compared to domestic production. By estimation less than 10 percent of maize seed used in the EU is imported from countries outside the EU.

Sugar beet seed

The figures compiled by Ceddia and Cerezo (2008) show Italy and France to be the main sugar beet seed producers in the EU. The EU does not import significant quantities of sugar beet seed from third countries.

In Italy, the area of sugar beet seed production ranged between 2,400 and 3,600 ha during the period 2000 to 2005. Almost the entire production (99 percent) occurs in the north, in Emilia Romagna. Italy is a net exporter of sugar beet seed, with annual exports of between 5,700 and 10,000 tons during the period 2000 to 2005. The main destinations for Italian seeds at this time were Germany (around 4,300 tons in 2005), Belgium (around 2,000 tons in 2005) and Denmark (around 1,300 tons in 2005). Italian imports of sugar beet seed originated from other EU countries, mainly Germany, the UK, Belgium and France.

In France, the annual area of sugar beet seed production was between 2,800 and 4,700 ha during the period 2000 to 2005. The foremost seed production regions are the south west, the south east, central and western France, while crop production is concentrated in the north of the country. Like Italy, France is a net exporter of sugar beet seeds (around 8,800 tons in 2005), mainly to other EU Countries such as Germany and the Netherlands.

Oilseed rape (OSR)

According to Ceddia and Cerezo (2008), Germany and France are the EU's primary producers of OSR seed, cultivating around 4,800 ha and 3,800 ha respectively in 2005. In France the area of OSR seed production increased from just over 3,000 ha in 2000 to around 3,800 ha in 2005. Seed production takes place predominantly in western and southwestern regions. In Germany, the area of OSR seed production increased from less than 3,000 ha in 2000 to 4,800 ha in 2005, concentrated overwhelmingly in the west and northwest of the country, in areas where OSR crops are also grown. A trend in recent years both in France and Germany is the increase in the production of hybrid seed (compared to open pollinating varieties), which is done to limit the use of farm-saved seed (currently around 35 percent of the OSR planted in France is farm-saved seed). OSR seed trade is mainly within the EU, with very small quantities of seeds being imported from or exported to third countries. Germany is the main importer of OSR seeds in the EU, mainly from France (around 1,600 tons in 2005) and Hungary (around 1,000 tons in 2005).

Soybean seed

Italy and Romania emerged in Ceddia and Cerezo's survey (2008) as the EU's largest soybean seed producers. In Italy, the area of soybean seed production increased from 4,000 ha in 2000 to 9,000 ha in 2005. In Romania, the total area of soybean seed production declined from 7,500 ha in 2000 to just over 2,000 ha in 2005. The decline in the area of soybean seed production in Romania was accompanied by an increase in the use of farm-saved seeds. Serbia is also an exporter of conventional soybean seeds into the EU. Both in Italy and in Romania the regions devoted to soybean seed production are also those regions growing soybean crops, so there is no regional segregation of crop and seed production. This is a fact of great significance, should the cultivation of GE soybeans ever be authorised in the EU.

Costs of co-existence in seed production

Ceddia and Cerezo's 2008 study suggests that Europe could be self-sufficient in production of seed for crops such as maize, oilseed rape or sugar beet. In the case of maize seed, for example, imports from third countries such as the US and Chile represent only a relatively small percentage of the overall market. Thus, EU agriculture is not per se dependent on seed imports, and higher requirements for seed purity would therefore not lead to scarcities. The significance of this is that contamination control measures at the seed



production level could be easily regulated and controlled by the EU, with positive knock-on effects for the whole food industry; in particular, demand for clean seeds could largely be met. Thus EU farming and food production could substantially benefit from EU regulations securing seed purity at the production stage.


The feasibility of establishing effective measures for safeguarding seed purity is related to the costs per crop, hectare and region and the thresholds chosen. Data from Messéan et al (2006) provides us with a foundation for exploring the specific impact of each factor. Messéan's team used a computer simulation to investigate the feasibility of imposing thresholds at 0.3 percent and 0.5 percent (unfortunately, therefore, data on the crucial 0.1 percent threshold are missing), and developed some worst case scenarios with GE and conventional crops of the same species being grown within one region during the seed propagation phase. Neither this study nor that of Kalaitzandonakes and Magnier (2004) aimed to investigate the feasibility of achieving 'zero' tolerance for AP of GE seeds in conventional seeds, so both studies have certain limitations regarding methodology and results. In the case of Kalaitzandonakes and Magnier (2004), data on which the conclusions were based have not been made available.

The study by Messéan et al (2006) considered the relative impact of alternative scenarios regarding the following three issues:

- GE plants integrated into the landscape (at 10 percent and 50 percent share of the relevant crop);
- Agricultural production system (GE, conventional and organic crops);
- AP of GE seeds in non-GE seed (at 0.1 percent and 0.9 percent for crop production, and 0.1 percent, 0.3 percent and 0.5 percent for seed production).

Tests were performed for maize, sugar beet and other crops, simulating the conditions of a maize-producing region in France.

Drift of pollen was identified as the most important source of contamination in seeds, so the Messéan team assessed the impact of distance between seed-producing plots and cropland. According to their results, seed purity under a threshold of 0.1 percent would not be achievable under current conditions if GE maize is grown in regions where seed production takes place. They also found that a 0.3 percent threshold could only be achieved with additional measures, and indeed that a threshold of 0.5 percent would be the minimum not requiring drastic changes in current production techniques.



The Messéan study calculated that the costs of achieving seed purity with AP of GE material below 0.3 percent under worst case scenarios would exceed 20 percent of the gross margin of seed producing farmers (calculated as € 1488/ha). These costs are dependent on several factors including field size, wind direction and the flowering time of the maize varieties. Given that all these conditions might vary from time to time and from region to region, Messéan et al. estimated that income losses per hectare might range between € 80 and € 483, even exceeding 40 percent of the gross margin in the worst cases. The authors argued that these additional costs might force farmers to move out of the seed production business. However, under average conditions where maize seed yield is 3.5 tons per hectare (Messéan et al. 2006) and seeding rate is 0.027 tons per hectare at the farm level (Oehmichen and Lütke Entrup, 1986), the additional cost of € 483 per hectare for seed producers would lead to a price increase of just € 5.4 per hectare for farmers. This increase in farmers' co-existence costs is quite marginal compared to the total farm-level co-existence costs (including isolation distances, cleaning machinery and so forth) of up to € 98.3 per hectare as calculated by Copeland et al. (2007) for maize in the Alsace region in France.

Messéan et al performed similar calculations for the production of sugar beet seed. They calculated a gross margin of € 3180 per hectare, against costs for sustaining a 0.3 percent threshold of € 197 per hectare which might, due to the increased complexity of necessary co-existence measures, double if a 0.1 percent threshold were introduced.

Kalaitzandonakes and Magnier (2004) generated cost estimates of achieving and maintaining seed purity under conditions typical in the USA. According to their calculations, the introduction of a 0.3 percent threshold for seed purity (there is no threshold in place today) would lead to a cost increase of about 35 percent for maize seed production. Their raw data was not publishable, since it consisted predominantly of confidential figures from producers of GE seeds such as Monsanto, Pioneer and Syngenta. Other results from smaller companies were more variable, but no detailed figures were provided for these cases either. Costs of implementing a sub-0.1 percent threshold were not investigated.

Messéan et al (2006) and Kalaitzandonakes and Magnier (2004) present high costs as a major hurdle for production of seeds with low ('zero') admixtures of GE components, but their results should be interpreted with great caution for the three following reasons:



- (1) So far, the published figures are not comprehensive and only partially useful; the non-publication of raw data in the Kalaitzandonakes and Magnier study erodes its reliability.
- (2) Data should be understood in the wider context of the seed market in recent years: significantly higher prices have been demanded by seed producers in the US especially in the case of patented GE seed (Then and Tippe, 2009). Nevertheless, industry is being quoted that prices in seeds might increase about 30-40 percent.¹⁴ This indicates that the market also might be able to bear higher costs for securing seed purity. Rough estimates indicate that strict conditions for seed purity would generate a rise in seed production costs of less than 10 percent (even according to the figures of Kalaitzandonakes and Magnier).
- (3) The data presented here are based on worst case scenarios. Since seed production is concentrated in certain regions, region-specific solutions are available which can be much more efficient and less costly. Specific regulation could be based on Article 26a of European Union Directive 2001/18.
- (4) Costs per hectare as estimated by Messéan et al (2006) are relatively small in the context of subsidies paid for agricultural production. The reallocation of subsidies is currently being discussed in the EU, and it should be considered whether seed production areas merit extra funds to support costs of maintaining seed purity at low thresholds. The total funds necessary for such a measure would be small because the total area of seed production is limited.

There is clearly a need for further and more targeted studies to spell out in finer detail concrete requirements for reaching a 0.1 percent threshold in maize and other crop plants; this was completely outside the scope of either the Messéan et al. or the Kalaitzandonakes and Magnier studies. Before any decision is taken, the costs of a 'zero' tolerance threshold for AP of GE seed must be properly assessed and compared to overall costs in the whole food production chain. The following two chapters of this report, which present and evaluate data from downstream markets, attempt to do just this.

¹⁴ "\$500 SEED?", Farm Industry News, 1st September 2008 by Mark Moore, available at: http://farministrynews.com/seed/0904_seed_university_prices/

5. THE SITUATION IN DOWNSTREAM MARKETS

Segregation has been successfully accomplished in the European food market for the last few years thanks to the introduction of requirements for traceability and labelling. Costs of segregation arise from measures to enable quality management and control; costs also arise for economic damages incurred as a result of contaminations. Substantial costs are borne on the level of agriculture and food processing. At present, freedom from GE ingredients is a general standard for organic and conventional food products in EU markets.

Regarding the feed market, segregation and labelling is not as well-developed as it is in the food market, but there is in some EU member states substantial interest in the feed supply being made free from GE components. Voluntary labelling systems have been established for animal-derived products from production systems free from GE organisms in countries like Germany and Austria. The current German government even advocates more comprehensive labelling on the European level, according to their official program published in November 2009.¹⁵ This could create new dynamics in negotiations on segregation and in market demand.

The regulatory framework in the EU

In the European Union, labelling is mandatory for all foods derived from or containing ingredients derived from organisms produced using gene technology. According to this approach, all food that consists of, contains or is produced from GE plants has to be labelled as such irrespective of the presence of modified protein or DNA (EU Regulation (EC) No 1829/2003).

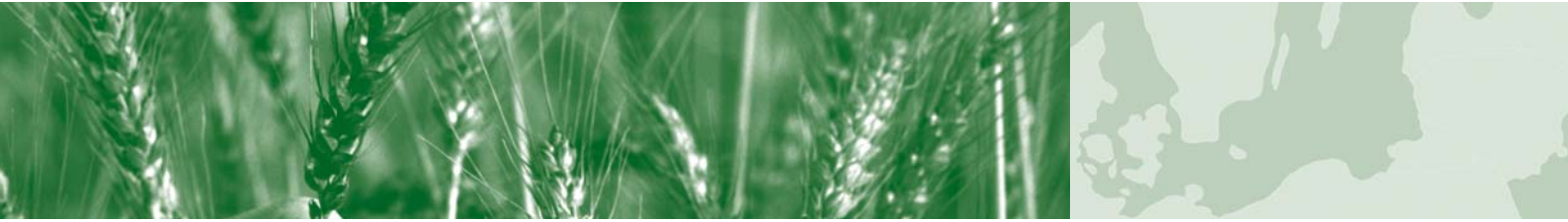
This labelling is not necessary in case of adventitious or technically unavoidable contaminations with authorised products below the threshold of 0.9 percent. This exception can only be applied, however, if operators have taken contractual measures to strictly limit the risks of the presence of material from GE plants, i.e. by an identity preservation scheme. Only under these conditions can the presence of such material be considered adventitious or technically unavoidable, and labelling omitted under the threshold of 0.9 percent.

For example, the European Commission's Standing Committee on the Food Chain and Animal Health (SCFAH) pointed out in its meeting of 16th June 2008 with regard to the implementation of Articles 12(3) and 24(3) of Regulation (EC) No 1829/2003:¹⁶

"There was a general agreement within the Committee that when operators have taken contractual precautions in order to strictly limit the risks of the presence of GM material, i.e. by an identity preservation

¹⁵ German Coalition agreement between CDU, CSU and FDP, adopted 26 October 2009, available at : <http://www.cdu.de/doc/pdfc/091026-koalitionsvertrag-cducsu-fdp.pdf>

¹⁶ Standing Committee on the Food Chain and Animal Health, Section: Genetically modified food and feed and environmental risk (2008), summary of the meeting held on 16th June 2008 http://ec.europa.eu/food/committees/regulatory/scfcah/modif_genet/index_en.htm



scheme, the possible presence of such material should be considered as adventitious or technically unavoidable and products have not to be labelled in accordance with Articles 13 and 25 if this presence is below 0.9 percent. This approach is valid for both products produced in the EU or imported from third countries."

For practical reasons, food processors and retailers delivering to the non-GE market must maintain internal standards far below this 0.9 percent threshold for quality and risk management. A producer that applies the 0.9 percent limit as an internal quality control standard would lose any flexibility in case of additional unintended contaminations, which can accumulate further on in the production process and result in economic damage and negative consequences for reputation. In practise, food producers and retailers set their own internal safety margins, establishing informal quality standards below 0.9 percent. In fact, 'zero' tolerance for traceable contaminations is a widespread basic standard for raw material in the EU, as confirmed by interviews with food producers conducted for the present study (see chapter 6). Certain minor contaminations might be accepted in some cases, but in most are not; allowing low level contamination with GE seeds by introducing thresholds for labelling could create major obstacles to safeguarding quality standards, which are necessary for the functioning of EU food markets. In other words, thresholds represent risk of economic damage not only in sensitive markets such as that for organic products, but also in many segments of the mainstream conventional food market.

Observers of the European food market agree that food producers in general try to avoid any product that would require labelling as being genetically engineered. For example, the European Economic and Social Committee points out in a 2004 Opinion paper that large retailers and branded food manufacturers in the EU build up "extensive quality assurance systems in which individual companies invest tens millions of Euros annually" (p. 21). Further, the paper states: "IP (Identity Preservation) and quality assurance systems also exist at processing plants, such as mills. Their customers at present expect purity guarantees between 0.1% and a maximum of 0.5%" (p. 20).

The strategy of European food producers reflects the general consumer rejection of GE food, and is used by the conventional as well as the organic sector. There is no signal that this approach will be changing within the next few years. In the case of sensitive food products, contaminations could even cause markets to collapse completely due to immediate consumer rejection.

Some data on costs in agriculture and food production

There is some published data available about the global costs of segregation in European and other markets. For example, the International Food & Agricultural Trade Policy Council (IPC) presented some figures at international negotiations concerning the Cartagena Protocol on Biodiversity, held in 2005. The presentation was designed to influence delegates from various countries to vote against a strict regime of segregation and labelling, so these figures should be treated with caution; nevertheless, they illuminate certain aspects of the global situation.

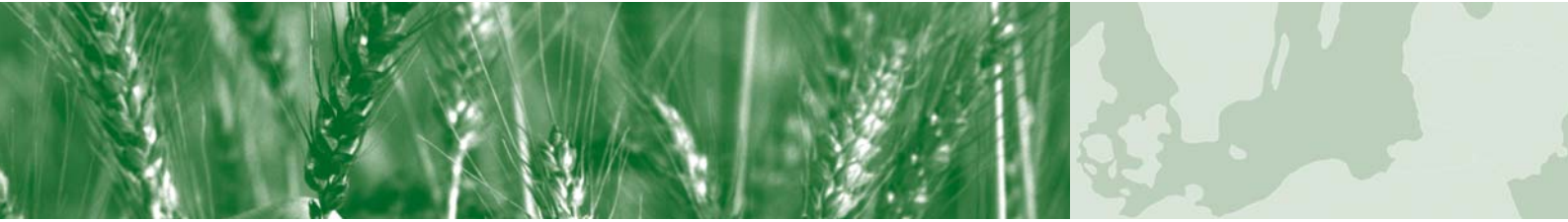
"If all 3,575 export cargoes of maize from the United States and Argentina were sampled and tested only once at loading, the total cost to indicate a cargo "may contain" LMOs [Living Modified Organism] would be \$1 million. If, on the other hand, exporters are required to identify and quantify individual varieties, as some countries have proposed, the labelling and testing costs for maize alone, from only these two countries of origin, could quadruple to \$4.4 million annually. If more extensive sampling is required, annual testing costs for maize alone could balloon to \$18 to \$87 million" (IPC 2005).

According to the IPC, the current costs in international trade of maintaining segregation for markets in the EU and Japan work out at US\$ 100 million per year:

"At present, the additional annual cost to consumers in Japan and Europe of acquiring non-LMO soybeans and maize approaches \$100 million."

Detailed information about costs for segregation and labelling on the level of food markets has been compiled in various studies; a 2005 study by Moschini, for example, shows that the cost of introducing GE wheat into the (EU) food market is likely to exceed potential economic benefits.

Farm level segregation and labelling costs have been compared to food market level costs in studies by Maciejczak (2009) and Menrad et al. (2009), who conducted their analyses in Poland and Germany, respectively. Their calculations of co-existence costs in an oilseed rape supply chain, based on computer simulations, show that farm-level costs are the most significant, mainly due to the implementation of isolation distances in the field as well as additional auditing and certification costs to protect production from contamination with GE organisms.



Gawron and Theuvsen (2007) estimated that implementation of strategies to avoid contaminations with GE seeds in oilseed rape processing in Germany would be associated with average additional costs of € 23.7 per ton. The most significant cost items are external analysis costs (≈4.79 per ton), documentation costs (€ 4.50 per ton) and additional personnel costs (€ 3.82 per ton).

Gryson et al (2008) addressed costs in the Belgian market for the GE organism free production of feed containing soybean meal. Additional costs, they note, comprise avoidance of GE plants in raw material, specialised production procedures and audits and analyses, amounting to an average of € 6.2 per ton (with variations depending upon the type of compound feed). Extrapolating to the sector level, segregation and co-existence measures represent an annual outlay of € 8.6 million for the soy sector of the Belgian feed industry. This is a conservative estimate, since calculations do not include a series of cost factors of which each operator would be expected to experience one or more: increased insurance fees; compensation payments in accidental contamination cases; monitoring; recalls; and governmental fines for incorrect labelling.

Costs of segregation in the German market

To find out more about the real cost of contamination cases and contamination prevention measures, the German Bund Ökologische Lebensmittelwirtschaft (BÖLW, roughly translatable as the Alliance for Ecological Food Economics) commissioned interviews with German food producers. The study, undertaken by Then and Lorch and published in 2009, involved ten producers from a range of market segments. This was not sufficient to provide a representative overview of the market, but nevertheless exemplified the diversity of measures necessitated and resources expended for avoidance of contamination in various stages of the food production chain. Evidence from the study suggests that costs would increase under a seed labelling regime that allowed contamination to become permanently entrenched in agricultural production.

Table 3: Selected costs for producers in different sectors of the German food market to avoid contamination with GE organisms (source: Then and Lorch, 2009)

Business	Annual quality check costs	Other annual costs	Necessary investments/damages
(1) Maize grain milling company (food products)	€ 50,000	Higher charges from grain producers: additional 10%	
(2) Frozen foods producer	€ 25,000		
(3) Organic food producer and bakery	€ 4,000	Training: € 2,000 Audits: € 1,000	Investments: € 65,000
(4) Organic producer of bread, meat and vegetables	€ 7,000	Training: € 1,500	Investments: € 5,000 Damages (cumulative) : € 7,000
(5) Partially organic dairy	€ 20,000	Storage/ segregation: € 1,000 Training: € 4,000 Audits: € 7,000 Higher charges from farmers: € 250,000 Product-related costs: additional 5-8%	Investments: € 180,000
(6) Organic producer of dairy and other food products		Product-related costs: additional 3-5%	
(7) Organic brewery	€ 2,500		Investments: € 10,000
(8) Partly organic (40%) producer of meat and meat products	Sampling and analyses: € 5,000-10,000 Documentation: € 2,500	Training: € 5,000 Higher costs for animal feed: € 360,000 (€ 6 / pig)	Investments (certification and capacity building for analysis): € 35,000
(9) Animal feed producer	€ 16,000	Training, audits € 2,000 Higher charges from farmers: € 160,000	Investments: approx. € 5,000
(10) Predominantly organic (90%) baby food producer	Sampling and analysis: € 5,000 Documentation: € 40,000	Training: € 35,000 Audits: € 5,000 Higher charges from upstream producers: € 770,000	Contamination damages: € 20,000

All these data emphasise that the EU food production chain depends upon effective mechanisms for segregation. Producers at all levels already face a substantial economic burden in preventing contamination with GE organisms and enabling genuine choice for consumers. Avoiding contamination from the earliest stage possible, i.e. that of seed, is one of the most effective ways of reducing economic damages and segregation costs. The importance of seed purity is also demonstrated by the case studies in the next chapter.



6. SPECIFIC CASE STUDIES

For this report, six detailed analyses were made of European companies involved in food production were performed, and their outcome is presented in the following six case studies. To conduct these analyses, a questionnaire for the producers was developed by the Swiss Research Institute for Organic Agriculture (FiBL, der Forschungsinstitut der Biologischen Landbau) and a series of personal interviews undertaken. The questionnaire addressed handling of commodities sensitive to contamination with GE organisms and segregation and testing strategies implemented. A particular focus was placed on measures implemented to avoid contamination and the corresponding additional costs. Anonymity was assured for all participants.

The case studies show strong demand for measures that maintain segregation at all stages of production, due to the increased costs incurred where permanent contamination is caused by zero-plus thresholds for labelling of AP of GE material in seeds. These costs represent a threat to the economics of food production within the EU. Case studies two, five and six show how heavily food production depends on seed purity; in these cases the producers went so far as to insist that seeds be tested before sowing.

Case 1: Milling company (Germany)

Commodity: maize

The mill is located in Germany and produces maize and wheat flour for non-organic food production. The commodity most sensitive to contamination with GE plants is maize, of which the company annually processes 40,000t. The company only processes commodities free from GE plants, with an internal safety margin of 0.5% threshold.

Extra commodity costs

In order to maintain the 0.5 percent threshold, the company purchases maize only from rural regions where no GE plants are grown (in this case, southern Germany). Furthermore, the company accepts maize from two to three suppliers which specifically contract farmers who can deliver uncontaminated maize. 80 percent of the farmers contracted have been delivering maize to the company for 13 years, so the supply chain is 'trained' to avoid contaminations. Even though the mill is working with contracts and long-term co-operation with trained supply chains, an average of one lot per year is rejected due to contamination above the 0.5 percent threshold. Contracting involves additional transactions which add € 20 per ton to commodity costs.

Testing costs

The commodity is delivered by truck. As the contamination risk is rated high, a reserve sample is taken from each truck delivering maize and the load from five trucks is stored separately in a quarantine silo cell (125t). From this quarantine cell, a sample is taken for a qualitative test for contamination. If the test is negative, the cell will be unblocked. If it is positive, the reserve samples taken from the trucks are then tested in order to identify the contaminator. The supplier of the contaminated delivery is obliged to take back the entire load of the isolation cell (125t) and charged for the additional costs incurred (cleaning, administration and so forth), even if parts of the load were delivered by another supplier. Output testing is implemented for the processed maize flour, which is qualitatively tested prior to loading. The total testing costs (input and output testing) amounted to € 76,800 per year.

Total co-existence costs

The aggregated annual prevention costs calculated for Case Study 1 in Germany amount to a total of € 876,800 at the mill level (see Table 4).

Table 4: Co-existence costs for preventing contaminations in maize flour at mill level (Germany)

Milling company - Case 1	Cost	Units	Percentage of total
A - Additional commodity costs	20.0	€ per ton	91.2%
B - Testing costs	1.9	€ per ton	8.8%
C - Depreciation of additional Storage	---	€ per ton	---
D - Cleaning / Flushing costs	---	€ per ton	---
E - Production stop costs	---	€ per ton	---
F - Education and training	---	€ per ton	---
G - Miscellaneous costs	---	€ per ton	---
Total prevention costs per ton of commodity	21.9	€ per ton	100.0%
Total prevention costs overall	876 800	€ per year	



The most single most significant cost is the additional commodity cost, which constitutes over 90 percent of total prevention costs. With a share of almost 8.8 percent, testing costs have far less relative importance. However, this cost calculation does not consider the case of commodity withdrawals which theoretically must be covered by the supplier who delivered the contaminated lot. This case is theoretical as no supplier can insure against the risk of contamination. Therefore, a case of contamination involves a high economic risk for the supplier which in turn means that the supplier might not be able to compensate damages incurred by the processor.

Case 2: Organic tofu processor (Germany)

Commodity: soybean

The organic tofu processor is located in Germany and produces organic tofu and tofu products. The commodities susceptible to contamination by GE plants are soybeans (1,800 tons per year), rapeseed oil (100 tons per year) and sweetcorn (15 tons per year). The company only processes organic commodities. A couple of years ago, the company switched its tolerance level for the adventitious and technically unavoidable presence of residues from GE plants from zero to 0.1 percent.

Extra commodity costs

In order to ensure the 0.1 percent threshold strategy works, the company a) purchases soybeans only on a contractual basis, from organic farmers in Europe (France, Germany, Italy) and Brazil (from the region Capanema in the state Parana, where no GE plants are grown), and b) provides contracted farmers with certified seeds from its own in-house seed propagation. Certification and contracting to ensure a GE-free commodity supply in addition to the provision of certified seeds results in additional commodity costs of € 20 per ton of soybeans.

Quality management costs

Recent problems from dust containing residues of GE plants in transport facilities required additional efforts in quality management. As a consequence, the company was forced to lift the internal tolerance threshold to 0.1 percent as well as to invest in additional working time for quality management and communication. Quality management and communication with suppliers and customers involves additional personnel costs of € 100,000 per year. Furthermore, continuous updating of quality management manuals and check lists causes additional costs of almost € 10,000 per year.

Testing costs

Commodities are delivered 50 percent by ship and to 50 percent by truck (in general, farmers make their own deliveries). Due to established contracts with farmers, close co-operation with an organic mill and a sound quality management system, risk of contamination is rated low. As a standard procedure a reserve sample is taken from each soybean delivery truck or container. Qualitative tests are analysed from each incoming container and from the load of six trucks which is stored in one silo cell (90t). The testing procedure involves additional labour costs of € 2,020 per year. Quantitative tests are only done in cases of a positive qualitative test. On average, about four qualitative tests per year are necessary. There are no extra costs with respect to output testing. The total testing costs (input testing) amount to € 9,837 per year.

Total co-existence costs

The aggregate annual prevention costs for the organic tofu processor amount to € 86.2 per ton of soybeans or a total of € 155,230 (see Table 5).

Table 5: Co-existence costs for preventing contaminations in soybean processing (Germany)

Processor - Case 2	Cost	Units	Percentage of total
A - Additional commodity costs	20.0	€ per ton	91.2%
B - Quality Management	60.7	€ per ton	70.5%
C - Testing costs	5.5	€ per ton	6.3%
D - Depreciation of add. Storage	---	€ per ton	---
E - Cleaning / Flushing costs	---	€ per ton	---
F - Production stop costs	---	€ per ton	---
G - Education and training	---	€ per ton	---
H - Miscellaneous costs	---	€ per ton	---
Total prevention costs	86.2	€ per ton	100.0%
Total prevention costs overall	155 230.4	€ per year	



As the company invests particularly in the prevention of contamination on the farm level, the most relevant costs are additional quality management costs which take a share of the total prevention costs of more than 70 percent. As a consequence, testing costs contribute only to 5.5 percent of the total prevention costs. Contrary to the situation in Case Study 1, the additional commodity costs account only for 23 percent of the total prevention cost. The reason for this is that the company purchases only organic soybeans and thus no extra premium is paid.

As soybeans constitute the basis of its business model, the unavailability of soybeans free from GE material would threaten the existence of this company. As the company already controls transport and storage to ensure non-admixture with conventional commodities, the highest risk is expected from seed contamination. It is because of this that the company even provides certified seeds to its farmers.

Case 3 : Milling company (France)

Commodities: organic corn, soybeans, soy cake

The mill is located in France and produces feed (100 percent organic) and baking flour (70 percent organic, 30 percent from untreated cereals). Commodities susceptible to contamination by GE plants are corn, soybeans and soy cake. The company only processes commodities free from genetically engineered plants (0.1 percent threshold with a 0.01 percent limit for detection).

Extra commodity costs

In order to ensure the 0.1 percent threshold can be maintained, the company purchases raw material only on contractual basis with specific conditions. Furthermore, the company demands audits from its suppliers and relevant analysis prior to purchase. The additional commodity costs for raw material amount to € 7,500 per ton.

Quality management and training costs

Quality management includes advice to farmers on best practise as well as training of staff. The total additional quality management costs amount to € 16,500.

Transport costs

Transport to the plant and internal transport are organised with company's own trucks and with external carriers. For external carriers, the company specifies detailed cleaning measures to be taken to prevent contamination. Cleanliness of trucks is checked by internal control procedures. This generates additional transport costs of € 7,500 per year.

Testing costs

Raw material is delivered by truck. Costs for taking reserve samples and for quantitative tests on contamination (15 input and 15 output tests per year) cause additional testing costs (input and output testing) of € 11,300.

Storage costs

Opportunity costs of separate silo cells and cleaning of the silos cause annual costs of € 5,500.

Total co-existence costs

The aggregated annual prevention costs calculated for the French mill in Case Study 3 amount to a total of € 48,300 at the mill level (see Table 6).

Table 6: Co-existence costs for preventing contaminations at mill level (France)

Milling company - Case 3	Cost	Units	Percentage of total
A - Additional commodity costs	7 500	€ per year	16%
B - Quality Management costs	16 500	€ per year	34%
C - Transport costs	7 500	€ per year	16%
C - Testing costs	11 300	€ per year	23%
D - Depreciation of add. Storage	---	€ per year	---
E - Cleaning / Flushing costs	5 500	€ per year	11%
E - Production stop costs	---	€ per year	---
F - Education and training (included in management costs)	--- Included in B	€ per year	---
G - Miscellaneous costs	---	€ per year	---
Total prevention costs	48 300	€ per year	100.0%



As the company runs a prevention strategy, most costs are the additional management costs which account for 34 percent of the total prevention costs. With a share of 23 percent, testing costs are also quite important. Additional commodity costs and transport costs account each for 16 percent of the total prevention costs while cleaning of silos and opportunity costs for storage accounts for 11 percent of the prevention costs.

The cost calculations do not include the case of commodity withdrawals and blocking of delivered raw material. Despite the efforts in implementation of actions and strict procedures, the risk of external contamination still exists and there is always a risk for the organic sector. Thus, the company remains extremely cautious and vigilant with respect to contamination with genetically engineered plants. The company stresses that any new authorisation of genetically engineered crops will cause further problems and will increase the risk for contaminations.

Case 4 : Organic food company (Germany)

Commodities: organic corn, soybeans, soy cake

The food company is located in Germany and produces different organic food products. The sensitive commodities processed are soy (ca 100 tons per year), maize (ca 100 tons per year) and flax (200 tons per year). The company only processes organic commodities and runs a zero tolerance strategy.

Extra commodity costs

In order to ensure the zero tolerance strategy, the company purchases organic raw material only on a contractual basis from organic farmers in Europe (France, Austria, Italy, Hungary) as well as in Canada, China and Brazil. There are no extra commodity costs specifically due to co-existence.

Additional purchasing costs

However, co-existence requires additional efforts with respect to information provision, communication and analysis of the situation of the suppliers. This involves additional personnel costs of € 50,000 per year.

Testing costs

Commodities are delivered by truck. As a standard procedure, a sample is taken from each truck which is qualitatively analysed. The total testing costs (input testing including labour) amount to € 4,250 per year.

Education and training costs

Personnel are continuously trained on relevant issues. The annual training costs amount to € 15,000.

Total co-existence costs

The aggregated annual contamination prevention costs of the organic food company in Germany amount to a total of € 69,250 (see Table 7).

Table 7: Co-existence costs for preventing contaminations in an organic food company (Germany)

Organic Food Company - Case 4	Cost	Units	Percentage of total
A - Additional commodity costs	---	€ per year	---
B - Purchasing costs	50 000	€ per year	72.2%
C - Testing costs	4 250	€ per year	6.1%
D - Depreciation of add. Storage	---	€ per year	---
E - Cleaning / Flushing costs	---	€ per year	---
F - Production stop costs	---	€ per year	---
G - Education and training	15 000	€ per year	21.7
H - Miscellaneous costs	---	€ per year	---
Total prevention costs	69 250	€ per year	100.0%



As the company invests particularly in the prevention of contamination on the farm level, the most significant costs are additional purchasing costs which constitute over 70 percent of total prevention costs. As a consequence, testing costs contribute only 6.1 percent of the total. Contrary to the situation in Case Studies 1 and 2, there are no additional commodity costs as the company purchases only organic commodities and thus no extra premium is paid.

In the future, the company expects that purchasing costs could increase due to the fact that some regions of origin might have to be excluded due to increasing contamination risk. This would require identifying and establishing contacts with new suppliers in order to ensure a reliable supply of contaminant-free raw materials. The company stresses problems with differences in sampling and testing methods. Thus, clear standards need to be defined. Currently, they observe that the upcoming GE traits are more difficult to detect and trace, and therefore they expect increasing costs for analyses.

Case 5 : Organic soy food processor (France)

Commodity: soybean

The soy food company is located in France and processes annually about 3,500 tons of soy of French origin. The company's quality specifications set a zero tolerance on the soy seeds before sowing and a 0.1 percent threshold on soybeans post-harvest. The company co-operates only with suppliers avoiding GE plants.

Extra commodity costs

In order to ensure zero tolerance or the 0.1 percent threshold strategy respectively, all seeds are analysed for contamination prior to sowing. Furthermore, before the raw material is delivered to the plant, the harvested soybeans are tested in storage. Moreover, the company runs a traceability procedure. Transport to the plant requires a cleaning certification of each truck. Contamination testing and the traceability system increase commodity costs by € 65 per ton.

Quality Management costs

The traceability system requires additional labour, for example for auditing of suppliers. The corresponding additional personnel costs are € 5 per ton of delivered raw material. Plant certification amounts to € 700 annually. So far, the company has never had a contaminated charge or lot.

Testing costs

Commodities are delivered only by truck. Additionally to contamination testing pre-sowing and in storage, each incoming delivery is tested. Due to the established quality management system, risk of contamination is rated low. Testing of delivered soy beans results in total testing costs (input testing) of € 6.8 per ton of raw material purchased.

Total co-existence costs

The aggregated prevention costs calculated for the soy food processor in France amount to a total of € 77 per ton of soybeans or € 269,398 in total per year (see Table 8).

Table 8: Co-existence costs for preventing contaminations in soybean processing (France)

Processor - Case 2	Cost	Units	Percentage of total
A - Additional commodity costs	65.2	€ per ton	84.5%
B - Quality Management	5.2	€ per ton	6.7%
C - Testing costs	6.8	€ per ton	8.8%
D - Depreciation of add. Storage	---	€ per ton	---
E - Cleaning / Flushing costs	---	€ per ton	---
F - Production stop costs	---	€ per ton	---
G - Education and training	---	€ per ton	---
H - Miscellaneous costs	---	€ per ton	---
Total prevention costs	77.0	€ per ton	100.0%
Total prevention costs overall	269 398	€ per year	



Due to the high quality specifications including zero tolerance for contamination in seeds, the farm level co-existence costs are the most significant cost category, amounting to almost 85 percent of the total prevention costs. On-plant testing and additional labour required for the quality management system (traceability) amount respectively to 6.7 percent and around 9 percent of the total prevention costs. To ensure the 0.1 percent contamination threshold, the company runs a comprehensive traceability and testing procedure on i) soya seeds, ii) soybeans after harvest (in storage) and iii) on each incoming delivery.

The company does not expect increasing problems to ensure the 0.1 percent threshold level provided that there is no cultivation of GE crops in France or in the region from where the company purchases soya.

Case 5 : Organic soy food processor (France)

Commodity: soybean

The processor is located in France and processes soybeans for food products. The commodity susceptible to contamination by GE plants is soya which is mainly of French origin and partly of Italian origin. On-plant segregation is organised spatially (separate silos for each quality) and by temporal / sequential segregation. Temporal segregation requires cleaning of the plant between organic and conventional processing. However as the entire plant is certified as being free from GE material, this cleaning procedure is not specifically related to the risk of contamination and thus does not involve additional costs. So far the company has not detected any contamination.

Extra commodity costs

The company's quality specifications require a contamination threshold of 0.01 percent. In order to ensure this 0.01 percent threshold strategy, the company's quality specifications require testing of each soya seed prior to sowing and post-harvest testing. The corresponding costs are included in the commodity prices. The company estimates the additional commodity costs resulting from testing, analysis for both seeds and post harvest raw material for soya to come to a total of € 30,000 per year. Transport to the plant requires a cleaning certification for each truck and the trucks must not have transported GE commodities just previously.

Quality management costs

The additional quality management consist of certification of the plant by an independent inspection body and of the auditing costs of each supplier. The total additional quality management costs amount to € 16,000 per year.

Testing costs

Commodities are delivered only by truck. Incoming deliveries are stored in separate silos. In order to increase traceability, separate silos are used for the lots coming from different suppliers. A list of authorised lots is provided by the suppliers. In cases wherein contamination is detected on the plant, the lot will be withdrawn at the supplier's expenses. Alternatively, the lot could be downgraded to feedstuff.

Genetic tests (PCR) are conducted on the trucks delivering soybeans to the plant. Also, samples are taken from the final products and analysed by PCR. The total PCR testing costs (input and output testing) amount to € 12,000 per year.

Total co-existence costs

The aggregated annual prevention costs calculated for the French processor amount to a total of € 58,000 (see Table 9).

Table 9: Co-existence costs for preventing contaminations in soybean processing (France)

Processor - Case 2	Cost	Units	Percentage of total
A - Additional commodity costs	30 000	€ per year	51.7%
B - Quality Management	16 000	€ per year	27.6%
C - Testing costs	12 000	€ per year	20.7%
D - Depreciation of add. Storage	---	€ per year	---
E - Cleaning / Flushing costs	---	€ per year	---
F - Production stop costs	---	€ per year	---
G - Education and training	---	€ per year	---
H - Miscellaneous costs	---	€ per year	---
Total prevention costs	58 000	€ per year	100.0%



The costs items A. and B. are indicative and can vary from year to year. Due to the high quality specifications, the additional co-existence costs are the most significant cost category amounting to 50 percent of the total prevention costs. On-plant testing and additional quality management costs amount to approximately a quarter each.

The company expects increasing problems in keeping the 0.01 percent threshold level unless conventional breeding from GE-free seeds is further developed. Furthermore, the company highlights the problem of stacked genes in newly authorised crops, which makes detection more difficult. This might lead to the necessity of increasing the internal contamination threshold. The company is in favor of a specific European GMO-free labelling regulation which would be at 0.1 percent for raw materials and finished products and 0.01 percent for seeds. If the threshold for seeds is higher than 0.01 percent, it will be more difficult to guarantee a low threshold for raw materials.

These six case studies from the EU food industry again exemplify that food producers already are facing considerable costs for maintaining their internal quality standards. Four of the six companies surveyed reduce the risk of GE crop contamination through contracting their suppliers. In all cases this results either in higher commodity costs (where the farmer is reimbursed for the necessary co-existence measures) or in higher purchasing or quality management costs (where the processor takes over some of the farm level costs). Thus, in all case studies the most relevant prevention cost categories are either additional commodity costs or additional purchasing / quality management costs. In some cases the food producers even invest directly for the maintenance of seed purity, showing the commercial significance of safeguarding standards. The integrated systems described here, which control all stages of farming and food production, are only suitable for certain companies in specific food production sectors. Not every food producer is in a powerful enough position to define seed quality through their own quality management systems; most depend instead upon general legal standards for labelling AP of GE seed. It is the task of the legislator, as reflected in EU regulations such as Article 26a of EU Directive 2001/18, to implement measures that prevent the presence of GE crops where they are not desired, and permit consumers to have a genuine choice.

7. IMPACT OF DIFFERENT LABELLING THRESHOLDS ON FARM PRODUCTION

Farmers operate between seed producers and food processors in the production chain; they have to deliver commodities with an AP of GE components below the thresholds given by the feed and food industry, and for this they depend on being able to obtain non-GE seed on the market. One of the key documents on the issue of the adventitious or technically unavoidable presence of GE seeds is the *Opinion of the Scientific Committee on Plants concerning the adventitious presence of GM seeds in conventional seeds (2001)*, written by the European Commission's Scientific Committee on Plants.

The Committee's Opinion presents calculations that show the likely extent of contamination built-up within farm production chains, starting with seed contamination levels of 0.3 percent and 0.5 percent. Figures are given for oilseed rape, maize and sugar beet (see Table 10). Taking into account that contamination can happen at different stages of farm activity, for example via pollen from neighbouring fields or residues in machinery and transport vehicles, it emerges that contamination in the harvest or crop delivered to the next operator in the production chain is likely to be considerably higher than the initial seed contamination levels of 0.3 percent or 0.5 percent.

The Committee's calculations do not extend to the entire food chain, but stop at the farm gate; it should be noted that there are possible sources of contamination arising after this stage, including transport, storage and processing.

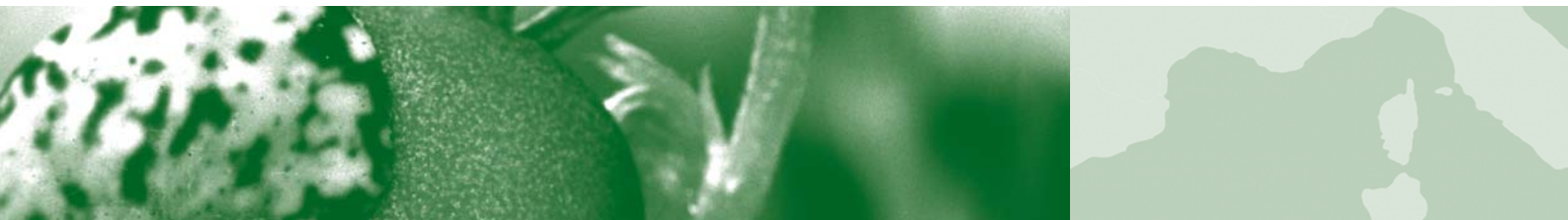


Table 10: Estimated average potential rates of adventitious presence occurring at various stages during farm production (Source: Scientific Committee on Plants, 2001)

	Oilseed rape (fully fertile)	Maize	Sugar beet
Seed	0.3%	0.3%	0.5%
Drilling	0%	0%	0%
Cultivation	0%	0%	0%
Cross pollination	0.2%	0.2%	0%
Volunteers	0.2%	0%	0.05%
Harvesting	0.01%	0.01%	0.01%
Transport	0.05%	0.01%	0.01%
Storage	0.05%	0.05%	0.1%
% achieved	0.81%	0.57%	0.67%

These figures from the Scientific Committee on Plants were the starting point from which this report set out to calculate potential impacts of AP labelling thresholds on farm production of maize and oilseed rape, extending to the food production chain beyond the farm gate. Economic impacts of different seed labelling thresholds were considered for three different scenarios projecting the demands of the EU food industry.

The results of these calculations are given in Tables 11 and 12. They are based on the assumption that farmers will only be able to sell their products to the European market if the labelling threshold of 0.9 percent in food can be met. The additional contamination likely to occur with seed labelling thresholds of 0.3 or 0.5 percent throughout the food chain suggests that introducing such thresholds will fundamentally threaten the economics of agricultural production in Europe.

As discussed above, industry tolerates only a very low level of contamination from GE crops in raw material. Given this fact, most commodities being affected by AP as presented in Table 10 will not satisfy quality standards in the EU food industry, and therefore financial losses for farmers and higher costs for food producers would be unavoidable if thresholds above 0.1 percent for labelling of AP of GE seeds were to be introduced.

Table 11: Impact of different levels of possible adventitious presence of GE seed in conventional and organic seed for maize, under three different scenarios for food industry and processor demands. (calculations based on figures generated by the Scientific Committee on Plants, 2001)

Input side: Possible AP of GE seed in non-GE seed*	Output side: three scenarios for maximum presence of GE components in agricultural raw materials accepted by food industry/processors E		
	0.10%	0.30%	0.50%
0.50%	Agricultural output fails industry standards (presence of GE components 0.77 %)	Agricultural output could pass industry standards only with special measures: (1) Use of special seed produced according to private standard with max. 0.1% GE seed traces and (2) Minimized cross pollination at 0.1% (presence of GE components 0.27%)	Agricultural output could pass industry standards only with special measures: (1) Use of special seed produced according to private standard with max. 0.1% GE seed traces (presence of GE components 0.37%)
0.30%	Agricultural output fails industry standards (presence of GE components 0.57 %)	Agricultural output could pass industry standards only with special measures: (1) Use of special seed produced according to private standard with max. 0.1% GE seed traces and (2) Minimized cross pollination at 0.1% (presence of GE components 0.27%)	Agricultural output could pass industry standards only with special measures (1) Use of special seed produced according to private standard with max. 0.1% GE seed traces and (achievable 0.37%) or (2) Minimized cross pollination at 0.1% (presence of GE components 0.47%)
0.10%	Agricultural output fails industry standards (presence of GE components 0.37 %)	Agricultural output could pass industry standards only with special measures: (1) Minimized cross pollination at 0.1% (presence of GE components 0.27%)	Agricultural output passes industry standards without extra measures: (presence of GE components 0.37%)

* Unlabelled AP at the described level could be due to a European labelling threshold or due to a general contamination in the bulk of seed without legislative labelling threshold

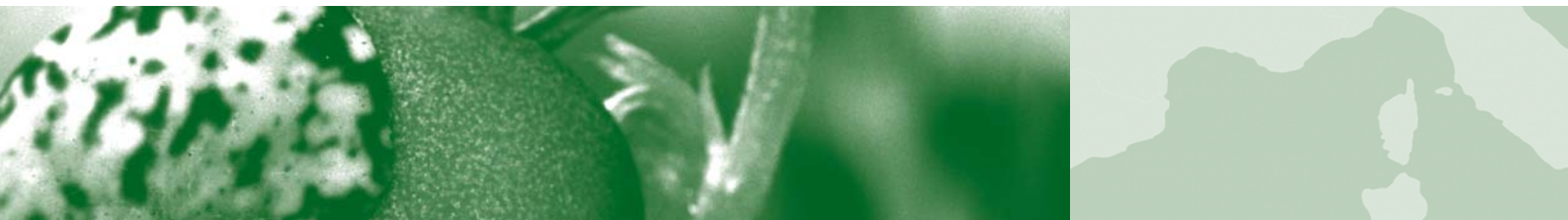



Table 12: Impact of different levels of possible adventitious presence of GE seed in conventional and organic seed for **oilseed**, rape under three different scenarios for food industry and processor demands. (calculations based on figures generated by the Scientific Committee on Plants, 2001)

Input side: Possible AP of GE seed in non GE seed*	Output side: Demands of the supplying food industry/processors concerning maximum accepted GE contamination of raw material			
	0.10%	0.30%	0.50%	0.70%
0.50%	Agricultural output fails industry standards (presence of GE components 1.01%)	Agricultural output fails industry standards (presence of GE components 1.01%)	Agricultural output fails industry standards (presence of GE components 1.01%)	Agricultural output fails industry standards (presence of GE components 1.01%)
0.30%	Agricultural output fails industry standards (presence of GE components 0.81%)	Agricultural output fails industry standards (presence of GE components 0.81%)	Agricultural output fails industry standards (presence of GE components 0.81%)	Agricultural output fails industry standards (presence of GE components 0.81%)
0.10%	Agricultural output fails industry standards (presence of GE components 0.61%)	Agricultural output fails industry standards (presence of GE components 0.61%)	Agricultural output fails industry standards (presence of GE components 0.61%)	Agricultural output fails industry standards (presence of GE components 0.61%)

* Unlabelled AP at the described level could be due to a European labelling threshold or due to a general contamination in the bulk of seed without legislative labelling threshold

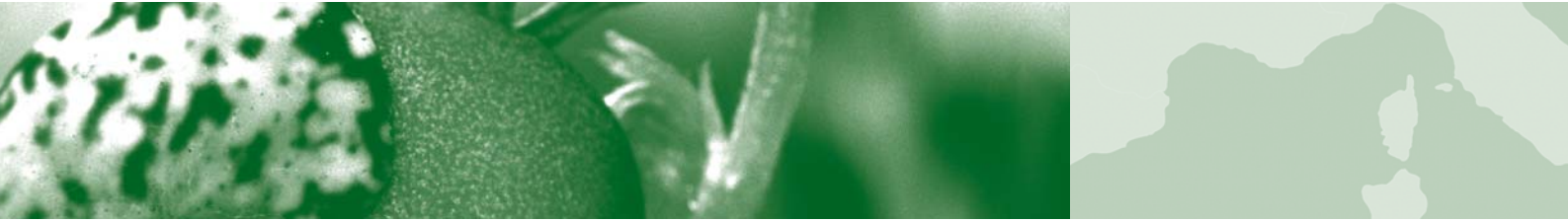


These calculations show that, if a threshold for the labelling of AP of GE seed in non-GE seed is set above 0.1 percent, food production free from GE components is not possible without expensive extra measures such as purchasing seed that is produced according to a private standard with a maximum contamination of 0.1 percent, and/or enlarged isolation distances and buffer strips to minimize cross pollination. There is solid reasoning behind the figures for the demand-side scenarios: were food processors to accept commodities with a burden of 0.6 or 0.8 percent adventitious admixtures, they might lose the necessary safety margin for avoiding intolerably high levels of GE material at the end of their own production process. At the very least, their flexibility would be reduced substantially, leading to higher costs (for example, for analyses or for supply agreements¹⁷ with defined quality specifications) and financial losses in the market due to rejection of batches with AP of GE material above or close to 0.9 percent).

With seed labelling thresholds of over 0.1 percent, entrenched contamination accumulating along the production chain would counteract producers' segregation and quality management efforts and increase their risk of infringing legal labelling thresholds. One possible result could be more limited consumer choice, if a significant number of producers conclude that they are not willing to bear this risk on a permanent basis, opting instead to simply stop producing non-GE products.

The reaction of European consumers, known to prefer non-GE plant products, could further complicate the situation for producers. Consumers may be unwilling to accept food that is sold without labelling but permanently contaminated to a level of around 0.5 percent, and possibly containing up to 0.9 percent GE material. It is necessary to admit the possibility that consumer rejection could cause certain sensitive markets to collapse, even if the formal requirements for not labelling the product as GE were being fulfilled.

¹⁷ Higher costs due to contracting suppliers result from additional transaction costs (identification of suppliers, negotiation, administration and supervision of contracts). Furthermore, processors might pay an incentive (price premium) to the contracted suppliers



Due to contamination occurring during cultivation, harvesting and transport, there can be substantial accumulation of GE plant material in the food production chain. Calculations of the economic impact of such accumulation, based on 2001 figures from the Scientific Committee on Plants, underline the eminent importance of seed purity for all further steps of farming and food production, and lead us to the conclusion that a sub-0.1 percent labelling threshold is necessary to safeguard the interests of food growers and producers in Europe.

Messéan et al. (2006) highlight the connection between seed purity and co-existence threshold values in their remarks about maize: "*(...) in a majority of situations, a 0.9% threshold can be achieved as long as proper machinery cleaning is performed and GM presence in seeds remains below 0.5%. This is mainly due to the fact that numerous fields are already isolated over the landscape.*" Astonishingly, practically no data exist on the impact of seed purity on either seed or commodity production, though a few important research publications stress the importance of seed purity for to coexistence (Eastham and Sweet, 2002; Flannery et al., 2005; Ireland et al., 2006; Smith and Register, 1998; Westgate et al., 2003). Devos et al. (2005) also point out that "*adventitious mixing may occur within a field owing to impure seed, while in nearly all experiments the seed was considered as genetically pure.*"

8. AVOIDING CONTAMINATIONS THROUGHOUT THE FOOD CHAIN

EU food market and consumer protection regulations aim to achieve a high level of transparency and traceability. Where GE crops are introduced into the market, co-existence with conventional crops and consumer choice are two fundamental concerns. This is reflected in European Union Regulation (EC) No 1829/2003 on genetically modified food and feed, and in the text of the EU Directive 2001/18 (amended in 2003 to comply with Regulation 1829/2003). Recital 28 of EU Regulation 1829/2003 reads:

“Operators should avoid the unintended presence of GMOs¹⁸ in other products. The Commission should gather information and develop on this basis guidelines on the coexistence of genetically modified, conventional and organic crops. Moreover, the Commission is invited to bring forward, as soon as possible, any further necessary proposal.”

Article 26a of Directive 2001/18 similarly emphasises the need for protection of co-existence:

“1. Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.

2. The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops.”

As was shown in the previous chapters, the seed stage of agricultural production is one of the most sensitive to contamination, but control of this stage is also one of the most effective ways to “avoid unintended presence of GMOs in other products”. There are no comprehensive investigations comparing the co-existence costs for the various levels of food and farm production. The European Commission has not yet undertaken any targeted initiatives to explore the feasibility, costs and benefits of establishing labelling thresholds for AP of GE seed below 0.1 percent; targeted investigations in this field should be made a priority in the future. So far there are only a few publications that allow comparison of the different stages of food production, including two discussed here. The first is a 2007 study by E. Neal Blue of the global economic losses caused by a major contamination event involving GE rice. The second is an investigation into the economics of co-existence and traceability in the German food industry, conducted by a team at

¹⁸ The legislation's use of “GM (Genetically Modified)” is equivalent to the term “GE (Genetically Engineered)” used throughout this study.



Weihenstephan University led by Klaus Menrad and published in 2009.

E. Neal Blue's study concerns the GE rice Liberty Link 601 (LL601), produced by Bayer CropScience but never officially deregulated by the US authorities. The study assesses the totality of downstream costs associated with the unintended release and spread of LL601 in 2006, the effects of which were global. Since LL601 entered the food chain without being authorised, the costs of contamination in this case are likely to exceed those caused by adventitious admixtures of authorised seeds. But what is of interest is the discovery of how costs are distributed. While Blue's figures rely partially on estimates, since some costs were future costs which would arise after the publication of the study, they nonetheless clearly show that seed producers (including the company BASF, which was affected by contamination of some non-GE seed lots) experienced relatively low costs, with much heavier burdens falling on elevators, processors, exporters and retailers (see Table 13). Rice farmers were affected in multiple ways, such as cessation of import orders from overseas markets and falling prices in futures markets, resulting in considerable financial losses. In 2009, US courts looked likely to make Bayer CropScience liable for around US\$ 1 billion compensation.¹⁹

Table 13: economic damage from LL601 contamination, by sector. (Source: Blue, 2007)

Loss Due to	Cost Lower Bound \$ millions	Cost Upper Bound \$ millions
Farm cleaning	2.172	3.259
Seed testing	2.088	2.088
Producers, foregone rice revenue in 2007	17423	17423
Loss of government payments due to shift out of rice	9.975	9.975
BASF reported losses	1.000	15.000
Processor/elevator cleaning & testing	87584	90.968
Direct export losses for 2006/07 crop year	254.041	254.041
Futur export losses (EU + Philippines)*	89.000	445.000
Retail product recalls in the EU	60.032	180.000
Retail product recalls : Philippines & Ghana	24.481	73.445
Export shipping losses	25.427	25.427
Loss due to price drop on futures market	168.000	168.000
Total Losses	741.223	1,284.626

Note: *Assuming closed EU and Philippine export markets from 1 year to 5 years.

¹⁹ "In *Bellwether Trial in Billion-Dollar MDL, St. Louis Jury Finds Bayer Liable for Contaminating U.S. Rice Crop*," *The AmLaw Litigation Daily*, published 4th December 2009
http://www.law.com/jsp/tal/digestTAL.jsp?id=1202436071420&in_Bellwether_Trial_in_BillionDollar_MDL_St_Louis_Jury_Finds_Bayer_Liable_for_Contaminating_US_Rice_Crop

In the study conducted by Menard's team at Weihenstephan University, it is enlightening to focus particularly on the comparison of co-existence costs for different parts of the wheat starch production chain. Examining relative costs for segregation by seed multipliers, farmers, grain elevators and processors, it is evident that co-existence and traceability measures are far less costly (adding less to the price of the end product) for seed multipliers than they are for actors at other stages.

Table 14: Costs of traceability and co-existence measures for non-GM wheat starch on the different levels

Level of the value chain	Measures to ensure co-existence and traceability	Additional cost: total cost (cost per ton)	Cost increase (% of product price on this level)	Additional remarks
Seed multiplier	<ul style="list-style-type: none"> ▪ Isolating fields ▪ Cleaning machinery ▪ Certification 	9.35 €/ha (1.75 €/t)	+ 2.5 %	<ul style="list-style-type: none"> ▪ Yield: 5.4 t/ha ▪ GM threshold 0.5 %
Farmer	<ul style="list-style-type: none"> ▪ Buffer zone of 20 m ▪ Cleaning of machinery ▪ On-field monitoring 	85.61 €/ha (10.85 €/t)	+ 7.2 %	<ul style="list-style-type: none"> ▪ Higher seed costs ▪ <i>Fusarium</i> resistant GM wheat ▪ Yield: 9.36 tons/ha (15 % yield increase) ▪ GM adoption rate: 50 %
Elevator	<ul style="list-style-type: none"> ▪ Higher costs of non-GM wheat ▪ Testing of incoming commodity 	^{1) 4)} 17,064,500 € (13.65 €/t) ^{3) 5)} 202,056 € (16.09 €/t)	+ 8.3 % + 9.8 %	<ul style="list-style-type: none"> ▪ Turnover with wheat: 711 Mio. € ▪ Proportion GM commodity: 50 % ▪ No imports of GM wheat
Wheat starch processor	<ul style="list-style-type: none"> ▪ Higher costs of non-GM wheat ▪ Testing of incoming commodity 	¹⁾ 2,583,590 € (20.84 €/t) ²⁾ 3,917,330 (39.17 €/t) ³⁾ 3,335,900 € (33.36 €/t)	+ 8.3 % + 12.5 % + 10.7 %	<ul style="list-style-type: none"> ▪ Turnover with wheat starch: 35.4 Mio. € ▪ Proportion GM commodity: 50 % ▪ Assumed 2 existing plants
1) Local separation 2) Spatial specialisation 3) Temporal specialisation 4) Big-sized company				



of the value chain in Germany Source (Menard et al., 2009)

These figures, along with the findings presented in previous chapters, suggest a strong economic rationale for a low ('zero') threshold in seed labelling. Under current practical and legal conditions in the EU, low ('zero') tolerance seed labelling thresholds greatly benefit the downstream processing and segregation of food, with a positive impact being felt in related markets. Costs saved at these stages of food production by far exceed additional costs generated at seed production level.

The lower the presence of GE seed at the beginning of the farming and food chain, the easier and less costly compliance with labelling thresholds avoidance of contaminations later on. Conversely, the introduction of persistent low-level contamination through positive labelling thresholds is expected to undermine consumer confidence, disrupt quality standards of food producers and undermine the economic basis of farmers. Thus, a 'zero' tolerance level for seed purity is critical for European food and farming, and should have priority in any political decision in the context of co-existence and consumer protection.

9. FURTHER ASPECTS OF RISK MANAGEMENT

According to the official position of the European Commission (2009), contamination of seeds with authorised GE traits is a matter not of specific risk for human health or the environment, but of purely economic relevance:

“Since the environmental and health aspects of GM crop cultivation are fully covered during their authorisation procedure, the issues to be addressed in the context of coexistence concern technical segregation measures and the possible economic consequences of admixing GM and non-GM crops.”

This statement does not take into account that products once authorised might be de-registered, withdrawn for quality reasons or their status altered at the national level by measures including bans. In accordance with EU Directive 2001/18 and European Union Regulation (EC) No 178/2002, authorisations of GE seeds must be re-evaluated and renewed every ten years based upon the results of monitoring and the latest scientific findings. In cases where the authorisation is not renewed, risk management requires effective mechanisms to reliably remove the product from the market. Further, Directive 2001/18 requires protection of the possibility of withdrawing any authorised products from the market should any new findings indicate risks to human health and the environment. These measures can also be implemented on the national level. In any case, the risk manager has to make sure it is feasible to organise complete withdrawal of de-registered seeds within a short period of time.

Various reasons for withdrawal or de-registration of GE crops can be listed. For example, the stability of traits and plant compounds might be affected by changing climate conditions. There could be silencing effects causing severe economic damage or even environmental risks if certain compounds are up- or down-regulated (see for example Dong & Li, 2007 or Bregitzer and Tonks, 2003). Environmental conditions might cause stresses that reveal traits in GM plants that had not previously appeared (Matthews et al., 2005). Most relevant for the risk manager is the possibility of new findings of unexpected human immunological reactions (such as allergies) to GE plants, as there are no reliable ways to anticipate thresholds at which these are triggered. There are some publications showing that immunological risks are not tested thoroughly by current EU risk assessment (see for example Valenta and Spoek, 2008). We might also see the emergence of new pests or weeds that require immediate reaction by the risk manager (Service, 2007; Catangui and Berg, 2006; Shengui, 2006).



Moreover, the possibility of new scientific findings on artificial plant compounds cannot be excluded. The current generation of GE seeds is closely related to compounds such as herbicides and insecticides; methods for assessing these chemicals are under constant development, so it is conceivable that new scientific evidence may emerge in light of which chemicals which had been approved as safe to use for many years no longer appear acceptable. The recent revision of the EU's pesticide directive provides various examples of such reversals.

This is also relevant for pesticide producing plants, such as Bt plants. Several toxins originally derived from *Bacillus thuringiensis* (the origin of the acronym 'Bt') are produced in GE plants such as maize and cotton. There is no reason to assume that risk analyses of Bt toxins (hitherto approved by EU authorities) are written in stone and will remain unchallenged in the future. The exact mode of action of the toxins (which is decisive for its selectivity) is still not fully understood, leaving room for speculation regarding their impact on the environment as well as on human and animal health. Recent publications on the mode of action of the toxin are contradictory: while Broderick (2006) argues that the presence of certain microorganisms were a prerequisite for the effectiveness of the toxin Cry1Ab in target organisms, Zhang (2005) cites a specific metabolic cascade as the main cause for the toxic effects of Cry1Ab (for review, see Then, 2009).

Hence, the need to withdraw GE crops initially found to be safe cannot be ruled out with sufficient plausibility. Such an assumption would certainly not comply with the precautionary principle, which forms the basis of legislation on GE crops in the European Union.

Several cases of discontinued crops can be found from the last decade (see Table 15 for world-wide examples). It should be noted that in any case, de-registration or market withdrawal after several years is a normal part of the life cycle for many GE plants, since they are, after all, technical products subject to innovation and product replacement.

Table 15: crops discontinued²⁰

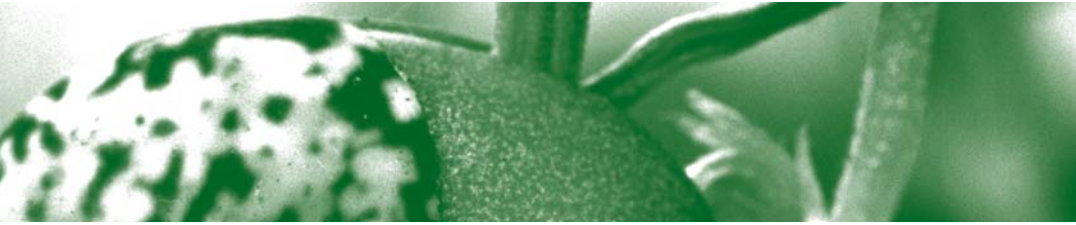
Crop / Trait	Reason for discontinuation
FlavrSavr tomato	Withdrawal because of quality problems
Zeneca tomato paste	Withdrawal because of consumer rejection
NewLeaf potato	Withdrawal because of rejection of food producers
Triffid Flax CDC	De-registration because of contamination risks
StarLink maize	Withdrawal because of potential health risks and food chain contamination
Bt 176 maize	Withdrawal because of potential risks for environment and problems in pest control

Thus, in practical terms, a strict distinction between authorised and non- authorised seeds does not seem to be suitable, since authorisation may be withdrawn at any time. It is in light of this that EU risk management requirements render it mandatory for seed purity to be maintained by a low ('zero') level threshold for labelling. The risk manager has to start from the hypothesis that GE seed will not be on the market in perpetuity, and that authorised seeds are liable to become technically outdated, withdrawn or de-registered for other reasons. Under these conditions low level thresholds or 'zero' tolerance for admixtures of GE seeds is a basic precondition for future production of seed and food, not only from the economic perspective of operators in farming and food production, but also from the risk management perspective of EU authorities. Furthermore, the risk manager must also be concerned with traceability and monitoring of seed, since authorised seed may be affected by legislative changes. This is dealt with in EU regulations such as Recital 3 of (EC) No 1829/2003:

"Traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects on human health, animal health or the environment, including ecosystems, are established, and the targeting of monitoring to examine potential effects on, in particular, the environment. Traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle."

On the basis of this and other relevant legislation, the European Commission position cited at the beginning of this chapter, stating the irrelevance of environmental and health concerns to co-existence and traceability measures, neither meets legal requirements nor takes account of ongoing discussions about the deficiencies of risk assessment standards for GE crops in the EU. For these reasons, it should be revised.

²⁰ Transgenic crops guide, Colorado State University, last updated 11 March 2004, available at: <http://www.cls.casa.colostate.edu/TransgenicCrops/defunct.html>




10. CONCLUSIONS

This report demonstrates that controls at the seed production and propagation phase in the food and farming industry are vitally important for the production of food and feed free from GE plant components. Segregation, traceability and appropriate co-existence measures are crucial to guarantee freedom of choice for farmers, food producers and consumers, and can be considered a fundamental requirement for the functioning of markets under the existing legal framework of the EU.

There is strong need for a low ('zero' at detection level) tolerance threshold for the adventitious presence of genetically engineered components in seed, and such a system also brings with it multiple benefits.

- **A low ('zero') level labelling threshold for AP of GE organisms in conventional seed meets the needs of European food market:** zero-tolerance brings substantial benefits for segregation in downstream farm and food production. Evidence for this can be found in the analyses of Blue (2007) and Menrad et al. (2009), as well as in the case studies performed for this report and in economic data on segregation costs in European and global markets. Higher tolerance thresholds in seed would significantly increase co-existence costs in downstream production, first and foremost for farmers, as their harvest has to meet strict thresholds set by the industry in order to maintain safety margins and meet consumer demand.
- **Low ('zero') level thresholds are feasible:** compared to food and agricultural production, seed production occupies small areas of land and is concentrated in certain regions. Costs of seed purity measures are significant but they can be limited by certain measures such as the clustering of seed production within regions that are subjected to specific regulations for co-existence. Further, it is favourable that specific measures for maintaining seed purity are in place anyway. The implementation of a low ('zero') tolerance threshold for AP of GE seed would be facilitated by the fact that measures already exist to preserve seed purity in the agricultural sector. These measures can be adapted to the needs of low (or 'zero') tolerance regime. It is also relevant that Europe could be largely self-sufficient in seed for the most important crop species (such as maize), making it easier to avoid problems related to contamination by imported seeds. These conclusions are based on studies by Messéan et al. (2006) and Ceddia and Cerezo (2008). In general, low thresholds at seed level are less costly than co-existence measures downstream.



A detailed study of the costs of implementing low ('zero') thresholds in certain crops could bring further clarifications.

- **Low ('zero') level thresholds are mandatory:** whereas contamination at other stages of farm or food production is limited to the lot or batch concerned, seed contaminations can be self-perpetuating and more resistant to decontamination measures. Thus, permanent contamination across the European seed stock due to unlabelled AP of GE seeds could lead to the loss of control and the inability to accomplish withdrawals. It can be concluded that the requirements of EU risk management make it mandatory that seed purity must be maintained by low ('zero') level thresholds for labelling. From EU regulations such as Article 26a of Directive 2001/18, seed purity can also be regarded as being mandatory to protect consumer choice.



11. RECOMMENDATIONS

This report has identified a need for the following investigations:

- Detailed breakdown of the costs of establishing low ('zero') tolerance seed labelling thresholds for different species in different regions, taking into account the possibility of regional or national measures such as non-GE seed production zones (based on Article 26 a of Directive 2001/18).
- Exhaustive analysis and representative survey of additional costs to the entire downstream food and feed production chain resulting from hidden contamination of seed.
- Detailed evaluation, based on case studies, of the implications of seed contamination for various risk management operations.

Based on the findings of this report, the following guidance is offered for further legislative steps at EU and national levels:

- In the case of plants such as oilseed rape whose pollination and seed characteristics could allow uncontrolled spread of genotypes through populations, the release of GE varieties should be banned on the basis that it could cause irreversible contamination of seeds.
- Minimum distances between cultivation sites enabling a low ('zero') tolerance threshold in seed production should be defined according to crop and region. A further appropriate measure could be the establishment of areas dedicated to conventional seed production from which the cultivation of GE crops is excluded (see for example the Austrian Agency for Health and Food Safety, 2004).
- Examination should be undertaken of EU financial mechanisms to support breeding, propagation and production of seed with 'zero' threshold.
- The "polluter pays" principle should be implemented through the organisation of a fund administered by state authorities and financed by companies that generate income from GE seeds.

Maintaining GE free seed should be a matter of priority, and one important safeguard is a 'zero' threshold for tolerating the adventitious and technically unavoidable presence of GE material in non-GE seed:

- Legal requirements for avoiding contaminations of seed and propagating material should be based upon the experience of the Austrian seed law.
- EU-wide technical requirements with respect to seed testing and sampling, including the accepted technical detection limit, have to be specified.

Definitions and abbreviations

AP:

Adventitious Presence. In this report, it refers to the accidental or unintended presence of genetically engineered organisms in non-genetically engineered organisms. EU legislation ((EC) No 1829/2003, Consideration 27) sets the following conditions for establishing adventitious presence: „(...)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.

GE:

Genetically Engineered; in this report, used synonymously with ‚GMO‘ (see below).

GMO:

Genetically Modified Organism, defined in EU legislation (Directive 2001/18/EC, Article 2) as, „an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination“.

‘Zero‘ threshold:

The zero threshold is defined in this report as it is in the Austrian seed law (Saatgut-Gentechnik Verordnung, 2001). The Austrian law requires complete absence of GE material from conventional and organic certified seed, but recognises that since sampling and testing methods are not perfectly accurate, a tiny quantity of contaminated material might escape detection. Using standard testing methods (i.e. those used in industry), if initial tests show no contamination, 95 percent of further tests will show results of between 0 and 0.1 percent. Thus, in practical terms, ‘perfect’ certainty of 0.0 is not achievable in standard industry tests; certainty is only achievable up to 0.1 percent. The threshold value of 0.0 means ‘not detectable using standard testing methods’. The value 0.1 refers to the level of contamination statistically expected in follow-up and control tests, consistent with the threshold value 0.0 in terms of methods and statistics (this value is referred to as the LQL, or Lower Quality Level).

References

- Blue, E.N., 2007:* Risky Business: Economic and regulatory impacts from the unintended release of genetically engineered rice varieties into the rice merchandising system of the US. Greenpeace International.
<http://www.greenpeace.org/international/press/reports/risky-business>
- Bock, A., Lheureux, K., Libeau, M., Nilsagard, H., Rodriguez-Cerezo, E., 2002:* Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture. IPTS Technical Report EUR20394EN.
http://www.gmfreeireland.org/downloads/gmcrops_co-existence.pdf
- Bregitzer P. & Tonks D., 2003:* Inheritance and Expression of the Transgenes in Barley. *Crop Science* 43 (1):4-12
- Broderick N.A., Raffa K.F. Handelsman J., 2006:* Midgut bacteria required for *Bacillus thuringiensis* insecticidal activity. *Proceedings of the National Academy of Sciences* 103(41): 15196-15199
- Catangui M. A. & Berg R. K., 2006:* Western Bean Cutworm, *Striacosta albicosta* (Smith) (Lepidoptera: Noctuidae), as a Potential Pest of Transgenic Cry1Ab *Bacillus thuringiensis* Corn Hybrids in South Dakota. *Environmental Entomology*, Jg. 35, H. 5, S.:1439-1452
- Ceddia, M. G., & Cerezo E.R., 2008:* A Descriptive Analysis of Conventional, Organic and GM Crop and Certified Seed Production in the EU. Joint Research Centre, Institute for Prospective Technological Studies , EUR 23443 EN, ISSN 1018-5593, ISBN 978-92-79-09563-4 , Scientific and Technical Research series
- Central Science Laboratory, 2007:* Adventitious traces of genetically modified seeds in conventional seed lots: current situation in member states. Research tender ENV.B.3/ETU/2006/0106rec.europa.eu/environment/biotechnology/pdf/seeds_study_2007.pdf
- Community Reference Laboratory, 2008:* Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing by the Community Reference Laboratory (CRL) for Food and Feed of the European Network of GMO Laboratories (ENGL) <http://gmo-crl.jrc.ec.europa.eu/guidancedocs.htm>
- Copeland, J. E., Daems, W., Demont, M., Dillen, K., Gylling, M., Kasamba, E., Mathijs, E., Menrad, K., Oehen, B., Petzoldt, M., Sausse, C., Stolze, M., Tollens, E., 2007:* Costs of measures to ensure coexistence and economic implications of adventitious admixtures in different systems. SIGMEA Sustainable Introduction of GM Crops into European Agriculture, Deliverable D5.2 & 5.3, Straubing
- Devos, Y., Reheul, D., & De Schrijver, A., 2005:* The Co-Existence between Transgenic and Non-Transgenic Maize in the European Union: A Focus on Pollen Flow and Cross-Fertilization. *Environmental Biosafety Research* 4:71-87
- Dong H.Z. & Li W.J., 2007:* Variability of Endotoxin expression in Bt Transgenic Cotton, *J. Agronomy and Crop Science* 193, 21-29
- Eastham, C. and Sweet, J., 2002:* Genetically Modified Organisms (Gmos): The Significance of Gene Flow through Pollen Transfer. European Environment Agency, Environmental issue report No. 28

European Food Safety Authority, 2004: Opinion of the Scientific Panel on Genetically Modified Organisms on the use of antibiotic resistance genes as marker genes in genetically modified plants. The EFSA Journal (2004) 48:1-18

European Food Safety Authority, 2009: Statement of EFSA on the consolidated presentation of opinions on the use of antibiotic resistance genes as marker genes in genetically modified plants, The EFSA Journal (2009) 1108:1-8

European Commission, 2009: Report from the Commission to the Council and the European Parliament on the coexistence of genetically modified crops with conventional and organic farming. [SEK(2009) 408], COM (2009) 153 final

European Parliament, European Council, 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. Official Journal of the European Union, L 106, 17/4/2001, pp. 1-38; Amended by Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003

European Parliament, European Council, EU Regulation (EC) No 1829/2003 of 22 September 2003 on genetically modified food and feed. Official Journal of the European Union, 18/10/2003, L268, pp 1-23

European Economic and Social Committee, 2004: Opinion on the "Co-existence between genetically modified crops, and conventional and organic crops", December 16, 2004, http://eescopinions.eesc.europa.eu/EESCopinionDocument.aspx?identifier=ces\nat\inat244\ces1656-2004_ac.doc&language=EN

Flannery, M.-L., Meade, C., & Mullins, E., 2005: Employing a Composite Gene-Flow Index to Numerically Quantify a Crop's Potential for Gene Flow: An Irish Perspective. Environmental Biosafety Research 4:29-43.

Flax Council of Canada, 2009: GMO Flax Update #1, REVISED, 28 September 2009 www.flaxcouncil.ca

GAO, United States Government Accountability Office, 2008: Report to the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, GENETICALLY ENGINEERED CROPS, www.gao.gov/cgi-bin/getrpt?GAO-09-60

Gawron, J. & Theuvsen, L., 2007: Costs of Processing Genetically Modified Organisms: Analysis of the Rapeseed and Corn Industries. German Association of Agricultural Economists (GEWISOLA) 47th Annual Conference, Weihenstephan, Germany, September 26-28

Gryson, N., Eeckhout, M., Neijens, T., 2008: Cost and benefits for the segregation of GM and non-GM compound feed. 12th EAAE Congress, Gent, Belgium

Health Canada, 1999: Novel Food Information - Food Biotechnology - Sulfonylurea tolerant flax, CDC TRIFFID - FP967, FD/OFB-098-047-A, October 1999 <http://www.agbios.com/docroot/decdocs/ofb-098-047-a.pdf>

International Food & Agricultural Trade Policy Council (IPC), 2005: Upcoming Decisions on the Biosafety Protocol Could Sharply Increase Food and Feed Costs: IPC Urges Governments to Weigh Costs Before Taking Decisions, International policy council

International Food & Agricultural Trade Policy Council (IPC), 2004: The Potential Impacts of the Biosafety Protocol on Agricultural Commodity Trade Prepared for the International Food & Agricultural Trade Policy Council. Issue Brief, 2004 <http://www.agritrade.org/Publications/IBs/Techy/BSP.pdf>

Ireland, D.S., Wilson, D.O., Westgate, M.E., Burris, J.S., & Lauer, M.J., 2006: Managing Reproductive Isolation in Hybrid Seed Corn Production. *Crop Science* 46 (4):1445-1455

Kalaitzandonakes, N & Magnier A., 2004: Biotech Labeling Standards and Compliance Costs in Seed Production. Choices (a publication of the American Agricultural Economics Association), 2nd quarter 2004

Leonhardt, C., Hartmann, J., Zimmermann, H., Hochegger, R., 2009: Endbericht über das Monitoring einer möglichen Verunreinigung mit zugelassenen und nicht zugelassenen Gentechnisch Veränderten Organismen (GVO) gemäß GVO-Überwachungs- und Monitoringplan bei Saatgut in der Saison 2007/2008. Bundesamt für Ernährungssicherheit <http://www.baes.gv.at/saat-pflanzgut/gvo/monitoringberichte/>

Lu B-R & Yang C., 2009: Gene flow from genetically modified rice to its wild relatives: Assessing potential ecological consequences, *Biotechnol Adv* (2009)doi:10.1016/j.biotechadv.2009.05.018

Maciejczak, M., 2009: Benefits and costs of co-existence between GM and non-GM supply chains. *Annals of the Polish Association of Agricultural and Agribusiness Economists*, Vol XI (6)

Matthews D, Jones H, Gans P, Coates St & Smith LMJ, 2005: Toxic secondary metabolite production in genetically modified potatoes in response to stress. *Journal of Agricultural and Food Chemistry*, 10.1021/jf050589r.

McHughen, A., 1998: USDA Petition for determination of nonregulated status under 7 CFR 340.6 <http://www.agbios.com/docroot/decdocs/04-225-005.pdf>

McHugen, A., Rowland, G.G., Holm, F.A., Bhatti R.S., Kenaschuk E.O., 1997: CDC Triffid transgenic flax, *Canadian Journal of Plant Science* 77:641-643

Menrad, K., Gabriel, A. and Zapilko, M., 2009: Cost of GMO-related co-existence and traceability systems in food production in Germany. International Association of Agricultural Economists Conference, Beijing, China, August 16-22, 2009.

Messéan, A, et al, 2006: New case studies on the co-existence of GM and non-GM crops in European agriculture. Joint Research Centre (DG JRC) of the European Commission, Technical Report EUR 22102 EN ISBN 92-79-01231-2

Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH, 2004: Die Produktion von Saatgut in abgegrenzten Erzeugungsprozessen zur Vermeidung einer Verunreinigung mit Gentechnisch Veränderten Organismen im Kontext mit der Koexistenz von konventioneller Landwirtschaft mit oder ohne GVO und ökologischer Landwirtschaft http://www.ages.at/uploads/media/gvo_koexistenz_ages_studie_neu_03.pdf

Oehmichen, J., Lütke Entrup, N., 1986: Lehrbuch des Pflanzenbaues. Band 2 Produktionstechnik. Parey Hamburg und Berlin.

Saatgut-Gentechnik Verordnung, 2001: Bundesgesetzblatt für die Republik Österreich, Jahrgang 2001, Teil II, page 2691-2692

Scientific Committee on Plants, 2001: Opinion of Scientific Committee on Plants concerning the adventitious presence of GM seeds in conventional seeds. Adopted by the Commission on 7 March 2001, SCP/GMO-Seed-Cont/002-Final http://ec.europa.eu/food/fs/sc/scp/out93_gmo_en.pdf

Service R. F., 2007: A growing threat down on the farm. *Science* 316:1114-1117.

Shenghui W., Just D.R., Pinstrup-Andersen P., 2006: Tarnishing Silver Bullets, Bt Technology Adoption, Bounded Rationality and the Outbreak of Secondary Pest Infestations in China. Selected Paper prepared for presentation at the American Agricultural Economics Association Annual Meeting Long Beach, CA, July 22-26, 2006

Smith, J.S.C. & Register, J.C., 1998: Genetic Purity and Testing Technologies for Seed Quality: A Company Perspective. *Seed Science Research* 8 (2):285-293.

Tolstrup, K.; Bode, S.; Boelt, B.; Buus, M.; Gylling, M.; Bach Holm, P.; Kjellsson, G.; Pederson, S.; Ostergard, H.; Mikkelsen, S., 2003: Report from the Danish Working Group on the co-existence of genetically modified crops with conventional and organic crops. Tjele: DIAS-Verlag

Then, C., 2009: Risk assessment of toxins derived from *Bacillus thuringiensis* - synergism, efficacy, and selectivity. *Environmental Science and Pollution Research* <http://dx.doi.org/10.1007/s11356-009-0208-3>

Then, C. & Tippe, R., 2009: The future of seeds and food under the growing threat of patents and market concentration. Coalition for No Patents on Seeds" http://www.no-patents-on-seeds.org/index.php?option=com_content&task=view&id=91&Itemid=42

Valenta R. & Spök A., 2008: Immunogenicity of GM peas, review of immune effects in mice fed on genetically modified peas and wider impacts for GM risk assessment. *BfN Skripten* 239, Bundesamt für Naturschutz

Westgate, M.E., Lizaso, J., & Batchelor, W., 2003: Quantitative Relationships between Pollen Shed Density and Grain Yield in Maize. *Crop Science* 43 (3): 934-942

Wilson A., Lathman J., Steinbrecher R., 2006: Transformation-induced mutations in transgenic plants: Analysis and biosafety implications. *Biotechnology and Genetic Engineering Reviews* 23:209-237

Zhang X., Candas M., Griko N.B., Rose-Young L., Bulla Jr. LA., 2006: A mechanism of cell death involving an adenylyl cyclase/PKA signaling pathway is induced by the Cry1Ab toxin of *Bacillus thuringiensis*. *Proceedings of the National Academy of Sciences (USA)* 103: 9897-

SEED: THE BEGINNING OF LIFE

Food production starts with seed. Therefore, the seed sector has set high standards to guarantee quality and purity. With the introduction of genetically engineered (GE) plants in agriculture, seed purity acquired a new meaning. The majority of consumers demand non-GE food, therefore producers need to continue delivering foods free from GE plants and their components; for this, seed that is free from GE fractions is no less than essential. In this way, GE-free seed is the basis of economic viability for the organic and conventional non-GE food sector.

Within the EU, the option of establishing labelling thresholds for the adventitious presence (AP) of GE organisms in conventional and organic seed has been under discussion for several years. It can be expected that the new Commission starting its work in early 2010 will come up with a legal proposal for a labelling regime between 2010 and 2014.

The level of the labelling threshold will have profound impacts on the future of farming with respect to the possibility of co-existence and consumer choice. Co-existence costs for farmers and the entire food chain will be influenced by the level of seed purity.

This study presents data enriched by detailed case studies affording an overview of the costs associated with avoiding GE components in seed and food production. It concludes that it is feasible to produce seed free from GE components and that high labelling thresholds in seed would cause tremendous costs for the co-existence throughout the food chain, even threatening food operators' ability to deliver to non-GE food markets at all. Finally, the study develops recommendations for an appropriate labelling threshold whereby consumer needs are served, and economic interests are balanced among operators throughout the production chain from the seed to the final product.



The IFOAM EU Group is the European working level within the International Federation of Organic Agriculture Movements. It brings together more than 340 organisations, associations and enterprises from all EU-27, EFTA and candidate countries. IFOAM's goal is the worldwide adoption of ecologically, socially and economically sound systems that are based on the principles of Organic Agriculture.