

The European Union's planned Directive regarding the adventitious presence of genetically modified organisms in Seeds

Draft Commission Directive ... amending Council Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/458/EEC and Decision 95/232/EEC as regards additional conditions and requirements concerning the presence of genetically modified seed in seed lots of non-genetically modified varieties and the details of the information required for labelling in the case of seeds of genetically modified varieties¹

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Executive Summary

Keeping conventional and organic agricultural production and goods free of genetically modified (GM) crops is a pre-requisite to guarantee freedom of choice between GM and non-GM products and production for consumers and farmers.

The first and single most important source of potential GM contamination of non-GM production are seeds. The European Commission proposes to establish threshold levels for contamination of conventional and organic seeds with genetically modified organisms (GMO) at 0,3 % for oilseed rape, 0,5 % for maize, sugar beet, potato, tomato, chicory and 0,7 % for soya. Below these thresholds seeds containing GM varieties would not have to be labelled as containing GMO.

Other GM contamination arising from pollen flow, contamination of machinery and facilities, volunteers persisting in the soil and transport will presumably occur only in the event and in the vicinity of commercial GM farming. They may be controlled there by maintaining separation distances, changing farming practices, cleaning of machinery and other measures. The remaining contamination of most crops (except oilseed rape) could be expected to stay at levels below the labelling threshold level of 0,9%, which has been recently established for adventitious contamination of food and feed products.

However, if GM contamination of between one third and two thirds of the permissible food and feed contamination level was induced already at the seed level, this would frequently result in contamination levels of the non-GM agricultural products at levels above or around the permitted thresholds.

Such a situation would require routine quantitative testing and documentation of the GM contamination level of all affected products along the food and feed production chain on a batch by batch basis. The costs of these tests and the risk of contamination above the acceptable threshold would by magnitudes exceed the costs of a strict purity regime for non-GM seeds at a reliable detection and certainty level.

In addition, risk management of GMO releases, monitoring and eventual withdrawal of GM varieties would be substantially undermined, if all non-GM seeds could contain GM varieties and spread them over the entire area of cultivation of the crop affected. The present state of knowledge about the ecological behaviour and fate of GM crops, especially over longer time and in different environments, including gene flow with wild relatives, survival in the soil and recombination with other GM crops (gene stacking) is still rudimentary. A precautionary approach, both ecologically and economically, is therefore appropriate.

The proposed contamination levels for seeds would impose unacceptable costs, risks and management measures upon the entire food production chain and threaten the recently established community system for approval, labelling and traceability of GMO.

These risks and costs can be avoided by keeping non-GM seeds free of GMO and establishing a seed purity standard at the reliable and practical detection level of 0,1%.

Introduction

In July 2003, the European Parliament and Council finally adopted Regulations on Labelling and Traceability of genetically modified food and feed², which are the strictest and most comprehensive GMO regulations world wide. On the same day, EU Commissioner David Byrne announced the Commission would introduce an additional Seed-Directive to specifically regulate the adventitious presence of GMO in conventional and organic seeds. The Commission had already proposed such legislation in July 2002, but postponed further decisions until final thresholds for food and feed were adopted. Now Byrne announced a new proposal "not substantially different from the one in 2002."

The proposed Directive would amend existing European Directives on seed production and marketing of different crops (oilseed rape, maize, beet, tomato, potato, soya) to include purity standards regarding genetically modified varieties. It stipulates that 0,3% of rape seed, 0,5% of maize, beet, tomato and potato and 0,7% of soya seeds could be genetically modified without having to be labelled as GM product, provided the contamination was "accidental or technically unavoidable" and the contaminating varieties are approved for cultivation and marketing within the European Union.

What may appear as a minute contamination level would actually mean that on the entire area planted to maize, tomato, beet and potato every 200th plant (oilseed rape 333th), i.e. billions of plants, could be a fertile GMO without the farmers using these seeds even knowing about it. No commercial seeds on the market would be guaranteed to be completely free of GMOs any more. Similar Directives for wheat and other grains, vegetables and fruits would follow as GM varieties of these crops where approved.

As seeds are at the beginning of the food chain and able to multiply, such thresholds would fundamentally change the conditions for farmers, processors, retailers and consumers to avoid genetically modified crops in the future. "Non-GM" would become a relative term assuming that all production of affected crops actually contained some GMOs. The Directive would also change the conditions of control and eventual recall of GMOs as well as the patterns of environmental dispersal of those GMOs, which can fertilise natural relatives. The permitted contamination would occur irrespective of whether GMOs are intentionally planted in the area or not.

This memorandum proposes a simple and practical alternative to such a risky and cost-intensive approach. **All non-GM seeds should be required to be free of GMOs at the reliable and practical detection level of 0,1%, in order to**

1. **guarantee freedom of choice for farmers, industry and consumers,**
2. **minimise the costs for farmers, trade, processors, retailers and the public of maintaining non-GM production at the established threshold levels for food and feed,**
3. **minimise environmental and health as well as economic risks and enable their practical management,**
4. **provide a pivotal pre-requisite for "co-existence" between GM and non-GM farming and food production.**

The freedom of choice and its thresholds

The freedom to choose whether or not to eat and to use genetically modified food and feed is the basic common political denominator of the European Commission, governments, industry, food-producers, retailers and consumers within the European Union regarding the contentious issue of introducing genetically modified crops on the European Market.

In order to ensure freedom of choice, the European Council and Parliament in July 2003 adopted Regulations for the approval, labelling and traceability of GMO in Food and Feed, which require all food and feed derived from GMO to be labelled, based on a stringent system of traceability. As the Commission explains *"traceability is defined as the ability to trace GMOs, and products produced from them, at all stages of their placing on the market throughout the production and distribution chains, facilitating control and also holding the potential to withdraw products if necessary. The obligation of traceability is designed to facilitate accurate labelling of the final product and to provide the means for inspection and control of labelling claims. It is a direct response to the voices of consumers who have made it clear that they want - and have a right - to make informed choices."*³

After long discussions between the Council and the Parliament, thresholds for the adventitious presence of GMO have been established, below which labelling is not required. *"In order to avoid over-labelling, European Ministers agreed that these requirements should only apply if the presence of the GMO in the final product is more than 0.9%, if it is adventitious and technically unavoidable,"*⁴ explains the Commission. The regulation also provides for the future establishment of lower thresholds in general or for individual GMO.

To serve their customers and fulfil their legal obligations, producers all along the food chain must have the same rights to full traceability, labelling and practical means to avoid GMO in the products they use. In order to ensure contamination in the final product does not exceed the threshold of 0,9% and complies with the conditions of its application (to prove that they are adventitious and technically unavoidable) producers, processors, traders and retailers require precise information about any contamination of a product or ingredient, which may contribute and add to contamination in their final product. In order to reliably achieve safe margins below the set thresholds processors and producers will also have to require internal purity standards well below the maximum of 0,9%.

The Commission now proposes another set of thresholds for the traceability and labelling of seeds, at the very beginning of the food production chain. These thresholds (0,3% - 0,7%) would amount to between one third and two thirds of the entire 0,9% margin. Hence the proposed Seed Directive would actually block access to - presumably available - information about the initial levels of contamination and the ability to effectively control them.

This is especially critical as contamination of seeds has the potential to increase via pollination and volunteer plants and through seeds which have persisted in the soil (e.g.

populations of volunteer oilseed rape plants can persist up to 10 years⁵). This is not the case at later stages of the process. The general statistical and mendelian methods that are available to predict the results of initial seed contamination are not sufficient to derive valid figures for individual seed lots and growing plots at the required level of precision.

A special situation arises in the organic food production and processing chain as European and world-wide organic standards, including EU Regulation 2092/91⁶ on organic production of agricultural products, require that no GM materials be used at all in organic production. Just as the guarantee not to use pesticides can not ensure 100% pesticide free products, adventitious contamination levels in organic products from cross-pollination or other external sources may have to be taken into account, if GMOs are cultivated in the neighbourhood. However, if organic farmers knew that seeds contain up to 0,7% GMO they could not actively use such seeds without breaching their own principles and standards.

Finally the proposed Seed Directive would actually actively establish that contamination levels of at least the proposed seed thresholds were unavoidable throughout the entire food production chain. As a result, suppliers would no longer have to prove that this contamination was unavoidable on a case by case basis, as prescribed in the Food and Feed Regulation.

Calculations at the borderline

The Commission's approach to establish the proposed seed thresholds was to identify the maximum allowable contamination of seeds which would still guarantee to stay below the labelling threshold of 0,9% for final products. This approach seems to assume that no additional contamination would occur after the primary production. It also tacitly converts the very maximum of adventitious contamination levels presently set by the Parliament and Council into expected standard contamination levels.

Upon request of the Commission the Scientific Committee on Plants (SCP) gave an Opinion in March 2001⁷ on this question, which it re-confirmed in January 2003. The Committee's opinion actually avoids a clear assessment as to whether and how reliably the proposed threshold levels would prevent contamination above 1 % in final products. (Since then the 1% food and feed threshold proposed by the Commission has been lowered by the Council and Parliament to 0,9%.)

In its opinion the SCP points to a lack of reliable concepts, data and experience and cautions that *"this opinion may need to be revised in the light of new scientific data"*. The scientists also speculate that *"achieving the 0.3 % and the 0.5 % thresholds will become increasingly difficult as GM crop production increases in Europe. In due course the 1% threshold set by the Commission may have to be revised."* The SCP is especially concerned about so called varietal association cultivars of oilseed rape, consisting of 80% male sterile plants where *"an approximately 5-fold amplification can be predicted"*, i.e. an initial 0,3% seed contamination would result in 1,5% contamination of the yield.

The scientists estimated average contamination levels to be expected for oilseed rape, maize and sugar beet, based upon the thresholds for seed proposed by the Commission at that time (Table 1). The Commission has since revised the proposed threshold for maize from 0,3% up to 0,5%. As the main basis of their calculations they referred to an "ongoing ESTO study", which has since been published by the European Unions Joint Research Centre, as "*Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture*" in May 2002.⁸ As the authors of this study write "*a combination of expert scientific opinion and computer models was used. (...) The absolute values provided by the models (e.g. when considering if a particular threshold can be respected) have to be taken with care, since the models are not yet fully validated with field data.*" Follow up studies have been commissioned to improve the reliability of these predictions, but are not yet available. At this point of confidence however even the given standard deviations from the calculated averages would provide for resulting products to exceed 0,9% contamination.

In addition, different scientific studies indicate that the rate of outcrossing can vary substantially depending on natural conditions (e.g. wind direction and strength, behaviour of bees and other pollinators, competitiveness of GM plants, seed persistence in soil etc.), cultivation (e.g. male sterile hybrids, size of fields, dispersal of contamination sources) and agricultural practise. Also the scientists concede: "(T)he SCP is also firmly of the opinion that (...) farm management and commercial production practices will influence the ability to achieve a 1% threshold in food and food ingredients."

Table 1: Estimated average potential rates of adventitious presence of GMO occurring at various stages during on farm production

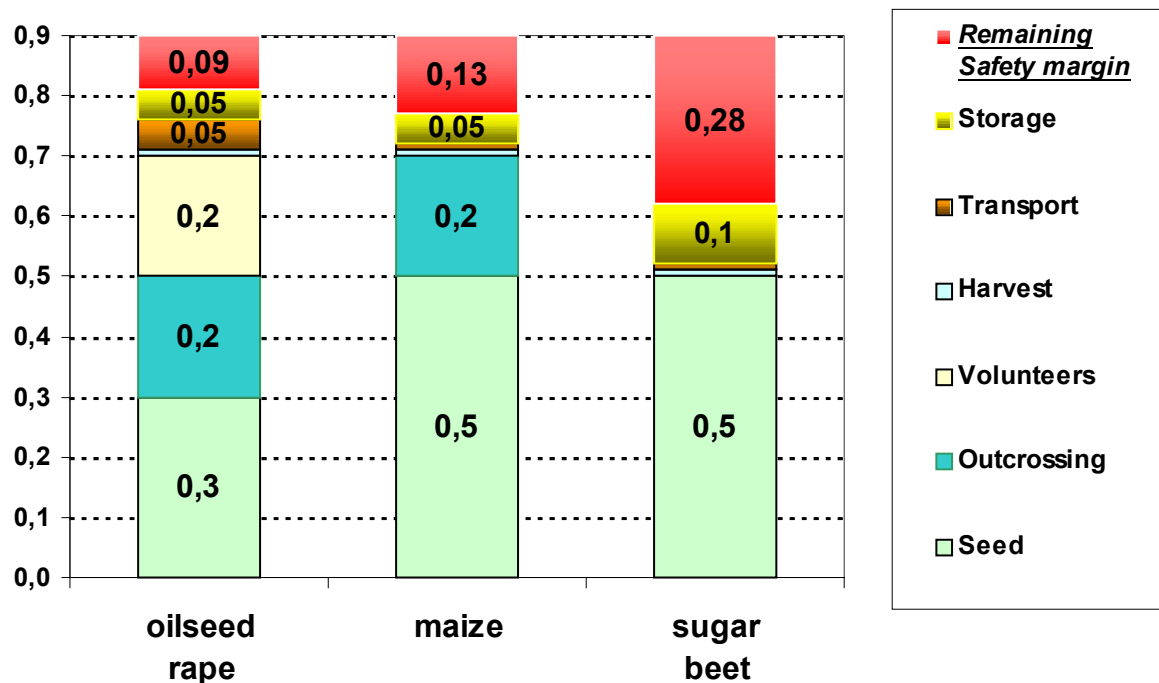
calculated by the EU Scientific Committee on Plants 2001 / 2003⁹

	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%	0,1%
Storage	0,05%	0,05%	0,01%
% achieved	0,81%	0,57%	0,67%

* The Commission has since changed the proposed threshold for Maize to from 0,3% to 0,5%
The Scientific Committee explains: "These figures are mean values and assume good agricultural practice including reasonable attempts to isolate crops and segregate products. The figures are largely derived from the ongoing ESTO study of the co-existence of GM and non-GM crops. The final % achieved is dependent on several variables."

Table 2: Remaining safety margins between seed thresholds and product thresholds, according to the Scientific Committee on Plants

Derived from the SCP figures (Table 1) and the new thresholds proposed by the Commission



Given the combination of extremely tight margins between 0,09% and 0,28% and the substantial uncertainties remaining it must be assumed that under the proposed thresholds for seeds the food threshold of 0,9% would be exceeded regularly already at the farm gate.

Conclusions

- To date there is no adequate scientific basis to reliably predict the cumulative practical risks and occurrence of contamination.*
- The statements of the Scientific Committee on Seed and the EU Joint Research Centre suggest that the proposed thresholds for seed contamination would result in contamination of agricultural non-GM products regularly exceeding the 0,9% threshold set for compulsory labelling.*
- Contamination levels could accumulate over time due to volunteers and long term seed persistence in the soil.*

Costs of Testing and Traceability

In order to determine whether products must be labelled as GM, traceability will be introduced throughout the production chain. This concept of "farm to fork" traceability not only relates to GMO ingredients, but is a general philosophy of the European Union's

approach to food safety and consumer information, established in 2002 through a Community Regulation "laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety"¹⁰, which will enter into full effect in 2005. It has been specified for GMO in the recently adopted Regulation on traceability and labelling of genetically modified organisms¹¹, which enters into force already in 2003. The regulation requires the transmission of specific information (either that the product contains or consists of GMOs or that it is a product of GMOs) with the product along the food chain requiring batch traceability in many cases and full documentation of the input and output of each business in the chain, to be kept for five years.

The Regulation also stipulates that for any GMO event approved within the EU a "unique identifier" has to be provided by the applicant as well as a method, which allows to test for the specific GMO. It will be usually provided in the form of a unique sequence of DNA (primers), which can be identified through Polymerase Chain Reaction (PCR) testing in a sample of the product.

PCR is a powerful and highly sensitive testing method, which can easily identify a single GMO in a sample of 10.000. The European Joint Research Centre has established a European Network of GMO Laboratories¹² to validate and standardise testing procedures and individual GMO tests. It currently consists of 44 EU enforcement laboratories, plus a number of observers. Standardisation and validation of the tests and availability of appropriate primers and reference materials are still under construction and not fully operational yet.

Another powerful testing method, called Enzyme-Linked Immunosorbent Assay (ELISA) uses antibodies to identify a specific protein, unique to a certain GMO. These tests are usually cheaper, require less equipment and skills and are typically used to screen for GMO presence. ELISA tests are presently not suitable to reliably quantify the presence of GMO at the required levels in products, but can be used for qualitative testing of seeds.

Quantitative testing for GMO contamination at levels between 0.1% and 0.9% can only be done by PCR methods at present. The standard approach to prove that a given sample is not contaminated with GMO is to first conduct a qualitative (yes/no) test for the presence of certain DNA sequences which are common to a large variety of GMOs. If such a screening test comes up with a positive result more specific tests will be required to identify the specific GMO varieties (approved/not approved) and to quantify their presence.¹³

As a rule, one PCR test only identifies and quantifies the presence or absence of one specific DNA sequence. As a result, in order to prove the absence of GM contamination and especially to quantify individual GM contamination levels the number of tests required will increase with the number of GMOs approved or not approved but potentially present in the sample.

Prices for qualitative screening tests at present range between 80 € and 180 €, while quantitative and GMO-specific tests range between 150 € and 400 €.¹⁴

Test results have two components: the detection and quantification of the presence of GMO material in a given sample (*detection level*) and the *confidence level* regarding the degree to which the test results are representative of the whole batch from which a sample was taken. The confidence level rises with the proportion of the batch sampled for testing. At the same time the costs of taking, shipping, processing, and testing of samples will rise with their size. 100% certainty could only be achieved, if the entire batch was tested, i.e. if there were no seeds left to be planted. Statistical calculations are carried out to determine sample sizes that will provide strong confidence in the results. For instance, using standard statistical sampling methods, a sample of 3000 kernels taken randomly from a large batch (10 to 25 tons according to OECD standards) whose true GMO content is 0.1% would render a probability of 95% that the sample would contain at least one GM kernel. If a 10.000 kernel sample were taken, the probability would raise to 99.995%.

Testing of GM contamination in seeds is a strait forward exercise aiming at the detection of individual GM seed entities. Testing of batches of processed products and semi-products can be a more complicated exercise. It has to deal with detection problems arising from the break down of DNA during processing. Also quantification becomes more complicated, as it must be calculated as a product of the total DNA (not individual kernels) present in a batch. The level of DNA can vary, depending on the number chromosomes (polyploidy) in the variety. Also different parts of a plant can contain different levels of the genetically modified DNA.

Conclusions

- 1. The extremely tight margins between the proposed seed contamination and the established food and feed labelling threshold of 0,9% would require application of expensive quantitative PCR testing methods to establish whether products are still below or already above the permitted thresholds**
- 2. The costs of testing will increase with the quantities and diversity of products to be tested**
- 3. Testing of seeds for the presence of any GMO contamination is the most reliable and cost effective way to exclude the major source of potential contamination in the food and feed production chain**

Impact on farmers

If the proposed Seed Directive entered into force, farmers would face a situation where they had to assume that the entire seed supply available on the market was contaminated up to the established seed labelling threshold level. Seed companies would give no guarantees of seed purity below these thresholds, even where there was no contamination. Any additional guarantees of purity, if available at all, would come at an extra price. This would also be true for breeding material.

However, the concept of traceability obliges farmers to inform their customers about GM contamination. It is most likely that traders, processors and retailers will require guarantees well below the maximum allowable threshold of 0,9%. This could create immediate problems, even where no "co-existence" with neighbouring GM planting occurs.

Special problems would occur where farmers save seeds for re-cultivation, given the potential of increased contamination levels in the second generation of the seeds, the persistence of seeds in the soil and the potential impact of GM volunteers.

If GM crops are planted in the vicinity of the farm non-GM farmers will face a more complicated situation, requiring a variety of additional measures to prevent cross-pollination, contamination of machinery, transport and storage facilities and control of volunteers. The European Commission has recently published *"Guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming"*¹⁵, which provide a long list of measures Member States could request and add to the general code of "good agricultural practice". These range from isolation distances, buffer zones, pollen barriers, suitable crop rotation, volunteer control, cleaning of machinery and separation of transport and storage facilities to co-operation between GM and non-GM farmers on rotation plans and sowing dates. However, the Commission makes no clear recommendations as to who should bear the costs of these measures and be responsible for their effective implementation.

A recent warning issued by the British Department for Environment, Food and Rural Affairs to farmers who had participated in farm scale trials of genetically modified oilseed rape in the UK sounds like a warning sign to all European farmers. The Defra ordered that no conventional oilseed could be planted on former GM testing sites, as "there is concern that seeds remaining in the ground from the GM trial will germinate and that the harvested crop might exceed the new EU thresholds on GM free crops."¹⁶

Regarding the issue of liability in the advent of contamination the Commission writes: *"Member States are advised to examine their civil liability laws to find out whether the existing national laws offer sufficient and equal possibilities in this regard. Farmers, seed suppliers and other operators should be fully informed about the liability criteria that apply in their country in the case of damage caused by admixture. In this context, Member States may want to explore the feasibility and usefulness of adapting existing insurance schemes, or setting up new schemes."* As a matter of fact under presently applicable general liability provisions in EU member states farmers, who have suffered a loss, would have to hire a lawyer, prove in detail their specific financial loss, demand compensation from the direct source of contamination (i.e. their neighbour!) and prove that this person has indeed caused the contamination and could have avoided to do so. "Soft assets" such as customers trust or the image of their product would hardly be eligible for financial compensation. Such lawsuits could require expensive expert testimony and take years to be resolved, if taken through different courts. The financial risk of such a lawsuit against a neighbour, who might well be backed by powerful GM companies law firms could outweigh the chances of substantial redress. In addition, such law suits would do little to

aid the co-operation between farmers required for co-existence between GM and non-GM crops.

In this context the purity of the seeds used would play an important role, as the farmer will have to prove that the contamination of his products did not (or not only) arise from his own seeds. In reality it may prove impossible for him to determine whether the seed company had sold him a faulty product or the contamination was caused by neighbouring GM crops.

Irrespective of the precise economic losses farmers may face from contamination and from the measures necessary to prevent such contamination, there seems to be no valid justification for imposing a technology and its risks upon farmers, who neither want to use this technology nor will have any benefits thereof.

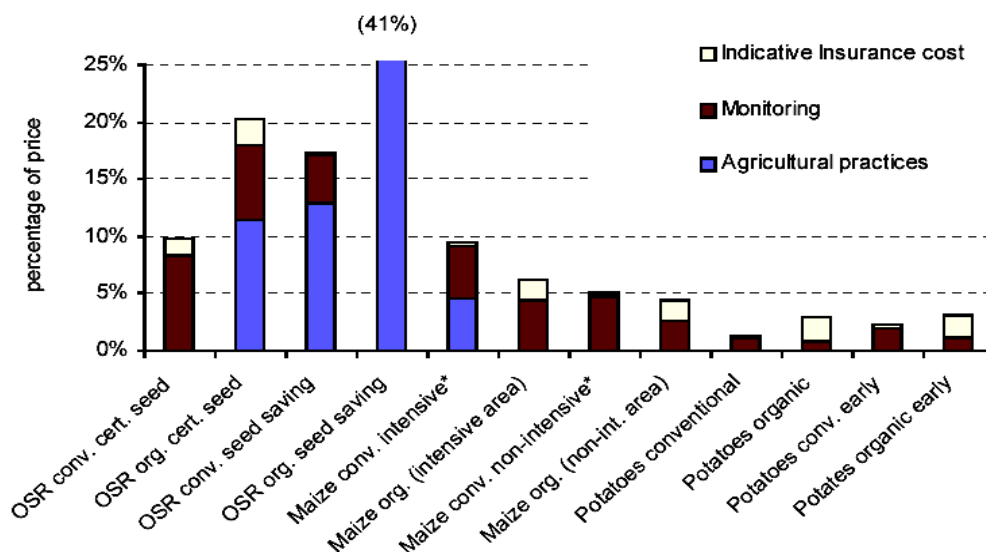
This is especially true for organic farmers. Organic principles and regulations categorically exclude the use of GMOs throughout the production chain. The use of seeds, which must be considered contaminated with GMOs, would therefore directly contravene the basic principles of organic farming. Organic certification schemes make a distinction between the use and the presence of traces of prohibited materials, such as pesticide residues, which may contaminate organic products due to wind drift and by other routes. Organic standards are based upon a stringent system of process certification, not on tests for the presence of individual ingredients. The forced introduction of GMO into the organic production chain would inevitably undermine the trust of customers, who expect organic products to be "gm free".

However, establishment of entirely separated organic breeding lines and seed reproduction with no GM contamination would not only prove extremely costly and be an unprofitable niche market for seed producers. It could also effectively de-couple organic seed development from the general research, development and progress in breeding.

In the unanimous opinion of all experts commercial production of GMOs in combination with mandatory labelling will raise the costs of production and processing of non-genetically-modified crops substantially. The study of the Joint Research Centre tried to predict these costs for different varieties and methods of production. A calculation involving many unknowns, which can only provide points of reference as the EU Commission pointed out, who has now commissioned a further study. Nevertheless, from the data available, general conclusions can be drawn on likely costs in the various sectors.

The JRC Study looked at the additional production costs for maize and potato *crop production* and for *seed production* of rape for different types of conventional farms and organic farms. For maize it based the estimate on a maximum level of seed contamination of 0.3% rather than 0.5%, as now proposed by the Commission. In this calculation the costs of segregation, testing and traceability at subsequent stages of processing and trade (beyond the farm gate) have not been included. Likewise the costs to public institutions, including tests, inspections, information gathering and dissemination, training, mediation and arbitration between farmers, documentation and customs formalities are not included.

Table 3: Estimation of additional agricultural production costs for various forms of production co-existing with GM crop production



Source: JRC, *Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture* ¹⁷

The JRC Study estimates the costs of additional measures to prevent GM contamination to range between 53 € and 345 € per hectare for conventional and organic farmers.

If non-GM seeds would remain practically free of GMOs, many of these problems could be avoided, most others would be significantly less threatening even in the case of "co-existence" between organic, conventional and GM crops.

Conclusions

1. *The right of farmers not to use GMO would be effectively voided.*
2. *Farmers would no longer be in a position to control and quantify the level of GM contamination in their production.*
3. *Serious levels of contamination would have to be expected in non-GM products even where there is no GM production in the neighbourhood.*
4. *However, labelling and traceability regulations will hold farmers liable for the eventual contamination of their products. Their customers will require purity levels below the 0,9% threshold for food and feed.*
5. *On farm seed reproduction would be associated with incalculable risks and therefore be severely restricted.*
6. *Costs of non-GM production would increase considerably, especially for smaller farm operations.*
7. *Organic farmers would be forced to abandon either their principles or their livelihoods.*

Impacts on traders, producers and processors

With the new Food and Feed Regulations entering into force around March 2004 non-GM certification will also be required for important food ingredients, which did not fall under the previous labelling requirements, such as oil, starch and sweeteners. Labelling will also be extended to feed products, which had been exempted so far. This will facilitate voluntary non-GM guarantees of producers of animal products such as meat, milk and eggs. While labelling of animal products produced with GMO feed is not required, non-GM guarantees are already being given by a growing number of companies.¹⁸

As the majority of European citizens refuse GMO in their food, most supermarket chains and major food brands have adopted a non-GM policy. As a result practically no food labelled as GM can be found in European supermarkets today.

Food processors and producers today can achieve this result by simply excluding affected ingredients originating from GM producing countries (USA, Argentina for soya and maize, Canada for oilseed rape) or by testing exclusively such imported ingredients before introducing them into their productions chain.

These simple and cost effective means to avoid GM ingredients would be seriously undermined by the proposed Seed Directive. Producers and processors along the food chain would have to seek and provide specific information and guarantees regarding the GMO contamination even of crops grown in areas with no GMO cultivation (presently the entire area of the EU with the exception of certain regions in Spain). This would have to include liability schemes, tests and means of traceability, which will ultimately amount to different forms of Identity Preservation (IP) systems. Such systems are well established for a diversity of quality requirements within the food chain and their share is generally expected to increase in the agricultural markets of the future. However IP systems come at an extra price, which has to be borne either by the customers or by other stakeholders within the production chain depending on the prevailing demand and supply situation on the market.

A study conducted by the European Commissions Directorate General for Agriculture on the Economic Impacts of Genetically Modified Crops on the Agri-Food Sector¹⁹ states: *"Identity Preservation is a move away from commodity trade and it implies additional cost at all stages of the food chain. According to the literature available they range between 5 and 25 €/t, depending on the product and the IP system, which represents 6 – 17% of the farmgate price of the different crops."* While the review does not provide conclusive figures and estimates regarding the total costs and their distribution, it clearly indicates that costs will actually have to be borne across the entire production chain. Customers however may not be inclined to pay a premium for a quality they take for granted so far and which provides no additional benefit but the absence of a hitherto unknown menace.

Non-GM IP systems for bulk commodity imports (soya, maize) are already available and have been applied to an increasing proportion of feed imports, but also of bulk ingredients such as oil and starch, even though labelling of these ingredients so far had not been

mandatory. They are available and in use for specialities such as lecithin and soy-protein and health products.

A "Technical Standard for the Supply of Identity Preserved Non-Genetically Modified Food Ingredients and Product" ²⁰, has been developed by the British Retail Consortium and Food and Drink Federation in 2001. Its manual lists on 60 pages requirements for seed merchants, growers, grain merchants, commodity agents, commodity processors and commodity and ingredient users delivering to the retailers. The Standards specify required preventive action, control, record keeping, documentation, sampling and testing. Sampling and quantitative PCR testing is recommended at the stages of seed, collection points, port facilities, discharge and storage at the various processing facilities and on the final product. In addition they require handling schemes, company policies and documented training of staff from suppliers. Some internal quality control standards of retail companies today require GM purity levels of 0,1% to accept the product.

Given their relative market strength food producers and retailers are used to require certain quality assurances from their suppliers at no additional costs. However this may prove difficult in a situation where the suppliers would be virtually unable to guarantee such qualities because they have no access to the necessary means (seeds) and information. Some major food and retail companies already reacted to similar problems (access to non-GM feed supply) in the past, using their market-influence and power to provide access for their suppliers to non-GM ingredients, which individual farmers would not have been able to acquire. Similar initiatives in the seed sector may ultimately prove to be the most cost effective means to avoid or reduce the necessity for detailed product testing of large quantities of products at various critical points, if legal provisions of the Seed Directive would not ensure the necessary qualities. Different practises of contract farming arising from this situation could have negative bearings on market-flexibility and prices.

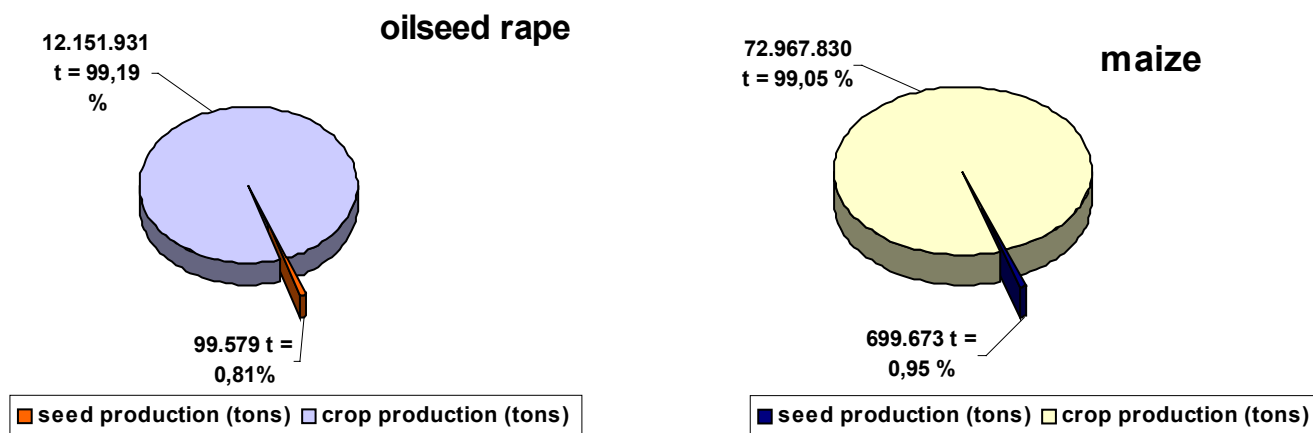
For certain products substitution with raw materials not derived from GMO affected crops (e.g. switching to other oils and fats than soybean and oilseed rape) has been a solution for non-GM quality management in the past for many products. This again can reduce market and price flexibility.

As the proposed Directive would establish a basic expectable contamination level for all affected products, cheaper and more reliable qualitative tests for the presence of GMO would yield positive results in an increasing number of cases. Additional quantitative tests would thus become a routine necessity at high prices and additional risks of false positive or false negative results within the statistical range of deviation.

When taking an overall look at the distribution of risks and costs of GM labelling the proposed Directive can be seen as an arbitrary intervention of the legislator to reserve over 50% of the 0,9% threshold level to seed companies, leaving only minute safety margins to processors and retailers and thus exponentially increasing the costs of compliance in a sector, which has to cope with quantities more than 100 times higher than those of the seed sector.

Table 4: Seed and crop production of maize and oilseed rape in the European Union (2001) in tons and as percentage

Source: FAO-Statistical Databases <http://apps.fao.org>



Conclusions

- 1. The smaller the safety margin between the threshold for seed and the threshold for food and feed, the higher the costs of control and testing throughout the entire production chain.***
- 2. While non-GM supply for food and feed ingredients can be achieved at minimal costs today, seed contamination thresholds between 0,3% and 0,7% would induce the necessity to establish costly and cumbersome systems of traceability and control, irrespective of whether GMO are commercially grown within the area of origin.***
- 3. In the advent of large scale GM cultivation within the EU seed thresholds between 0,3% and 0,7% would be the single most important source of contamination, which would regularly push the expectable levels of contamination in areas of GM planting to the limits and beyond the established labelling threshold for food and feed.***
- 4. To provide their customers with non-GM products at the most cost efficient rate, processors, producers and retailers may be forced to directly intervene in order to provide their suppliers with the necessary means to keep their products below acceptable contamination levels at their own risk and expense.***

Impact on Seed companies

At this moment nearly all seed lots tested regularly by seed authorities in EU member states contain no GM contamination or at least contamination levels below 0,1%. This is also the case for seeds imported from outside the EU, including the USA.

Seed purity standards, which range between 98% and 99,9% for different varieties and qualities of seed, are one of the key features of seed production and seed companies have highly sophisticated protocols and methods to achieve the necessary standards. Preventive measures to protect both production of basic seeds and reproduction of certified seeds for sale are well established and legally regulated.²¹ Present practice already includes also routine DNA testing of the adventitious presence of GMOs for sensitive crops.

The Commissions proposed Directive would therefor rather relax than tighten the presently observed standards for non GM seed production, especially for companies, which reproduce seeds in the vicinity of GMO sources (from commercial planting of GM crops as well as commercial reproduction of GM seeds in third countries).

It is obvious that seed companies will have to extend the necessary measures to avoid adventitious cross-pollination and other sources of GM contamination, if large scale GMO planting will occur in the vicinity of their operations. This will include maintenance of safety distances as well as time periods between GMO and non-GMO planting. Additional measures regarding safety distances and crop rotation periods had initially been foreseen by the Commission within the proposed Seed-Directive, but were dropped upon the request of the seed companies. The control measures necessary will also include routine testing of the seed material at different critical points of development and use.

While these tests can presently be confined to qualitative (yes/no) testing for the presence of GM material, the setting of threshold levels for allowable contamination would imply quantitative testing of the seed lots. Seed companies would therefor exactly know the level of contamination of their seeds in any case. However, the proposed Directive would allow them to withhold this information from their customers, if the contamination was below the proposed thresholds.

Depending on the crop, to achieve purity standards of 99,9% may not be an easy exercise for seed producers. Such purity standards however do exist already in present seed legislation for some varieties of basic seeds (e.g. oilseed rape: 99,9% for basic and 99,7% for certified seeds)²². As opposed to general purity standards however, GM purity standards would exclusively refer to the single condition of contaminants not being genetically engineered and not to other potential forms of contamination (other seeds, inert material).

In Austria, where seed purity standards of 0,1% are legally established, no major problems have occurred over the past two years.²³ Maize seed production in Austria, as a result of these stringent purity standards prevailing, have actually doubled between 2000 and 2002.

Seed companies argue that such standards could no longer be achieved, if the seeds were to be produced in the vicinity of large scale GMO cultivation. In this respect it should be noted that substantial amounts of seeds with no contamination are presently being imported into the European Union from the United States of America, where GMO

cultivation is widespread and also from countries such as Chile, where both GM and non-GM seeds are produced.

While separation distances, pollen barriers and other conventional means to prevent contamination would most likely be sufficient for the production of maize, potato and soya, special problems may arise in the case of oilseed rape and sugar beet.

For certain problematic seed production (e.g. virus free potato) it is not unusual and already legally foreseen to designate areas for seed production, where the cultivation of potentially contaminating crops is excluded. In the event of large scale cultivation of GMOs such measures may be necessary to protect the integrity of seed production. The establishment of so called "GMO free Zones" could be one way to achieve this goal.

The European seed market has undergone massive concentration during the past decades. However there is still a large and vivid community of small and medium size seed companies. These companies might be economically more stressed by the additional measures necessary to prevent adventitious contamination as they do not have the same flexibility regarding the location of their seed production as transnational companies and because the additional fix costs for testing and traceability would relate to smaller production quantities. In order to counter these market asymmetries and to protect small and medium size seed companies within the European Union special support and fair means of distributing the additional costs between the different market players should be considered.

As pointed out above on farm reproduction of seeds, which is common practice for oilseed, potatoes and other crops, would be associated with additional risks of contamination for farmers, if the contamination level of the initial seeds used is unknown. This would result in additional sales of certified seeds and an increase of income for seed companies at the expense of farmers.

Finally it should be noted that the largest seed companies on the European market are transnational companies, which want to introduce GMOs on the EU market and actively lobby for a deregulation of the present conditions of GMO marketing both regarding their safety assessment and their labelling. It appears only fair and common sense to hold those companies reliable for the purity of non-GM production in the first place. Given the background of most of these companies as agro-chemical producers, they also have a track record of pushing contamination thresholds to the upper limits and to routinely plead innocent until proven guilty regarding environmental and health impacts of their products.

As labelling standards have been identified as the major obstacle to marketing GMOs in an adverse consumer environment, GMO producing companies have a vested interest in pushing labelling thresholds as high as possible, if they cannot be avoided all together. One of the major concerns regarding the proposed Seed Directive is that the ubiquitous presence of GMO in non-GM varieties could threaten the long term feasibility of the present food and feed labelling threshold. Such an effect would actually be in the interest of those companies wishing to market GMO varieties. It therefore does not appear inconceivable that these seed companies would actively use the threshold margins offered by the Commissions proposal for this purpose.

Conclusions

- 1. At present seed companies are in a position to keep seeds clean of GM contamination at the reliable detection and confidence level of 0,1%.**
- 2. Seed companies already have in place sophisticated traceability and testing systems, which could be adapted to the additional requirements. Testing for non-GM seed purity at or close to the level of 0,1% will be inevitable in any case.**
- 3. Under conditions of "coexistence" with large scale GM cultivation additional measures to prevent contamination of basic seeds and certified seeds will become necessary, depending on the specific conditions for different crops.**
- 4. Designation of sufficiently isolated areas for seed reproduction, as already used for other purposes, may prove necessary to guarantee seed purity.**
- 5. Increased costs of pure seed production will be a fraction of the costs incurred by wide spread seed contamination. As they will affect only a comparatively small number of companies, measures for compensation would be uncomplicated.**

Impacts on environmental protection and risk management

The proposed allowance for contamination of conventional and organic seed with GMOs, as envisaged by the draft Seed Directive, would constitute a special form of large scale GMO releases, not anticipated in the framework of Directive 2001/18 on the deliberate release of GMOs ²⁴ and the new Regulation on genetically modified food and feed.

Directive 2001/18 provides a framework for the approval of commercial cultivation of GM varieties on clearly identified and potentially restricted areas. Directive 2001/18 requires *inter alia* a specification of the area and the conditions of the release of a GMO. However, the proposed Seed-Directive would lead to widespread uncontrolled releases of GMOs across all areas planted to the crops concerned.

Monitoring of GMO releases and a public registry of fields planted to specific GMOs as prescribed by Directive 2001/18 would become extremely difficult if not impossible. It would also become impossible to reliably protect nature conservation areas or other ecologically sensitive areas from GMO gene flow, as this would imply to prevent any growing of crops in their vicinity, which might be contaminated with GM varieties, not just GMO varieties.

Directive 2001/18 also allows for GMO approvals only for a limited time, after which the approval will have to be renewed or expires. If a GMO has been dispersed to a large

diversity of non-GM varieties, an effective withdrawal after expiry of the approval would be most difficult and cumbersome. However, the proposed thresholds would only apply to GM varieties which are actually approved under EU law and no threshold levels would be allowed for GM varieties, which are no longer approved.

Furthermore cross-pollination of different GM varieties may result in the creation of new GM varieties, which would "stack" different GM traits. Such crops would have to be treated as new GMO events, not approved within the framework of EU regulations. They would constitute an illegal contamination for which no thresholds are set (the thresholds for seeds as well as products only refer to GMO, which have been approved under EU legislation). The EU Commission so far has not come forward with practical suggestions how to deal with the emergence of such new GMO.

The proposed levels of continuous background emissions of GMO would substantially increase the probability of this uncontrolled recombination of different GMO. Such "natural" recombination of different GM varieties have already led to multiple-resistant varieties in Canada and the USA, creating agricultural problems to control such "superweeds". They could as well lead to the development of unexpected new properties and environmental behaviour in such "secondary" GMOs. A general rule regarding the survival of GM varieties or their traits assumes that they would only become invasive, if their trait entailed a valid competitive advantage. Whether and how such advantages may develop as a transgenic trait is incorporated into other than the initial target varieties has not been studied and is hard to predict.

Most importantly, the proposed Seed-Directive would substantially affect emergency measures to recall an approved GMO, in case additional information on negative impacts on the environment, human or animal health would be revealed. The GMO would have to be traced back and withdrawn from all varieties and seed stock, which could be contaminated. With the threshold levels proposed by the Commission this could be literally all seed stock and varieties of the affected crop. Obviously such a situation would constitute a major crisis for the seed supply. A complete withdrawal of the GMO would be an extremely difficult, costly and lengthy operation. Questions arise to what extent such a recall could be effectively accomplished at all.

The single large scale experience with such a recall refers to a GM maize variety "Starlink" in the USA, which is suspected to have an allergic potential. Despite a ban and country wide seizures of contaminated yields and seed batches, which cost hundreds of millions of Dollars, cases of contamination were still reported in the second harvest after this operation. This situation occurred after only two years of use of the "Starlink" variety on a very low level.²⁵

Conclusions

- 1. The Commission's proposal to establish general tolerance levels for GMO contamination in conventional and organic seed would effectively induce a new type of large-scale releases of GMO, which could neither be properly monitored nor recalled and is not foreseen in EU legislation on the deliberate release of GMO.***

- 2. *The Seed-Directive would make the legal provisions of Directive 2001/18 concerning the authorisation, monitoring and eventual withdrawal of a GMO substantially more difficult, if not impossible, to enforce.***

Legal Basis of the Commission-Directive

Without going into the full details of the legal questions at stake, it can be summarised that the Commission proposes to implement the proposed Seed-Directive on the legal basis of a so called "Comitology procedure" ²⁶, based on Article 202 of the Treaty, which provides for the Council to confer on the Commission the power to implement rules adopted by the Council.

The proposal pretends to technically adapt six different Directives of the Council and the Parliament on the marketing of different types of seeds (beet, vegetables, potatoes, oil and fibre plants, fodder plants, cereals). Under the proposed "management procedure" the Commission would propose the Directive to a "Standing Committee on Seeds", composed of representatives of the member states. This Committee would vote on the proposal with qualified majority. If the proposal was adopted the Directive would enter into force. If the proposal was not adopted the Commission would have to inform the Council of Ministers, which can take a decision by qualified majority. The Commission however would not be obliged to defer the application of the measures until such a decision is taken.

The proposed Seed Directive appears to actually contradict the rules adopted by the Parliament and the Council regarding the release of genetically modified organisms in Directive 2001/18. It would substantially change the meaning of key provisions within this Directive, such as monitoring and withdrawal and protection of sensitive areas. It is therefor suggested that the European Institutions involved (Member States and the European Parliament) should challenge the legal basis of the proposed Seed-Directive. Such far reaching decisions regarding the safety of the environment and health as well as basic conditions of farming should not be made in technical Committees, but put before the European public and its legitimate representatives and be decided upon by the Parliament and the Council of the European Union.

Finally, it should be borne in mind that, in addition to authorisation under Directive 2001/18, a genetically modified variety must be approved under national and European Plant Variety Protection legislation as any other variety. Approvals may be refused and have been refused either at national or at European level for good agricultural and specific regional reasons beyond the safety issues, exclusively covered by Directive 2001/18. However the proposed Seed-Directive would allow for contamination with any GM variety authorised under Directive 2001/18. It would thus open up the possibility of contamination with varieties, which are actually not approved for commercial introduction under national or European Seed legislation.

Conclusions

1. ***The measures proposed by the Commission contradict key provisions of Directive 2001/18.***
2. ***The far reaching decisions proposed by the Commission cannot be the legally based upon a technical "Comitology Procedure" but require a formal co-decision of the Council and the Parliament of the European Community.***

Legislative proposal

Within Community law it is the exclusive privilege of the European Commission to submit legislative proposals to the Council of Ministers and the European Parliament as well as to derived institutions such as the Standing Committee. For this reason the following suggestion is leaning closely to the proposed Commission proposal, even though a more general legislative approach based on a different legal instrument might appear more appropriate.

In order to achieve the proposed purity level of non-GM seeds, the following changes to the proposed Commission-Directive (SANCO/1542/02July2002) should be made in its Annexes I (page 6), II (page 10), III (page 11), IV (page 14), V (page 16), VII (page 20) respectively:

1)

>> (2) In Annex I, part B the following sections are inserted after section 1:

"1a Presence of genetically modified seed: Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I Part A and B section 1, seed of a non-genetically modified variety may contain not more than 0.1% of genetically modified seeds.

In order to verify this purity level, genetically modified varieties must not be detectable in the first testing of a seed lot and must not exceed an 0,1% threshold in follow up tests conducted in the course of control measures.

The presence of such seed in follow up tests must however be adventitious or technically unavoidable. In order to establish that the presence of this material is adventitious or technically unavoidable, producers must be in a position to supply evidence to satisfy the Member State that they have taken appropriate steps to avoid the presence of genetically modified organisms." <<

2)

Within the rest of the text the figure of "0,5 percent" (or 0,3% or 0,7% respectively) should be replaced by "0,1 percent" throughout the entire text.

3)

An additional provision should be inserted at the appropriate place stipulating that "Any seed labelled as containing or consisting of genetically modified varieties, irrespective of their level, must be placed on the market according to the legal provisions for the placing on the market of genetically modified seeds in general and, where applicable, according to any specific provisions for the placing on the market of the specific event of genetic modification contained in these seed."

References

- ¹ Draft Commission Directive .../Ecof ... amending Council Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/458/EEC and Decision 95/232/EEC as regards additional conditions and requirements concerning the presence of genetically modified seed in seed lots of non-genetically modified varieties and the details of the information required for labelling in the case of seeds of genetically modified varieties, Brussels, 02.07.2002, P./secr/doc2001/va/1542en02july2002
http://www.zs-l.de/gmo/downloads/Seed_Directive_3_July_2002.pdf
- ² Regulation (EC) No.../2003 of the European Parliament and of the Council of...on genetically modified food and feed, adopted in July 2003. The final version of the Regulation has not been published yet. An inofficial version can be downloaded at http://www.zs-l.de/gmo/news/food_feed_final.pdf
 Hereafter referred to as Food and Feed Regulation
- ³ Commissioner David Byrne, "GM food and feed: A new regulatory framework ahead on authorisation, labelling and traceability" in Consumer voice, Special Edition, April 2003
http://europa.eu.int/comm/dgs/health_consumer/newsletter/200305/consumervoice_en.pdf
- ⁴ "GM food and feed: A new regulatory framework ahead on authorisation, labelling and traceability", Consumer voice, Special Edition, April 2003
http://europa.eu.int/comm/dgs/health_consumer/newsletter/200305/consumervoice_en.pdf
- ⁵ Eastham, K. & Sweet, J. (2002) Genetically modified organisms (GMOs): the significance of gene flow through pollen transfer. Expert's Corner Series, European Environment Agency, Copenhagen.
- ⁶ Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, Official Journal L 198 , 22/07/1991, consolidated text:
http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31991R2092&model=quichett
- ⁷ Opinion of the Scientific Committee on Plants concerning the adventitious presence of GM seeds in conventional seeds. (Opinion adopted by the Committee on 7 March 2001)
http://europa.eu.int/comm/food/fs/sc/scp/out93_gmo_en.pdf
 For an overview and membership of the Committee see http://europa.eu.int/comm/food/fs/sc/scp/index_en.html
- ⁸ EU Joint Research Center, various scientists, "Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture, May 2002." Hereafter referred to as "JRC Study"
http://www.jrc.cec.eu.int/download/gmcrops_coexistence.pdf
- ⁹ Opinion of the Scientific Committee on Plants concerning the adventitious presence of GM seeds in conventional seeds, page 8
- ¹⁰ Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
http://www.efsa.eu.int/pdf/En_Base.pdf
- ¹¹ Regulation (EC) No .../2003 of the European Parliament and Council on traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, soon to be published. The latest version before final adoption can be found at:
http://wwwdb.europarl.eu.int/oeil/oeil_ViewDNL.ProcViewCTX?lang=2&procid=5476&HighlighType=2&Highlight_Text=traceability
 Hereafter referred to as Traceability Regulation
- ¹² The homepage of ENGL is available at <http://engl.jrc.it/>
- ¹³ During routine testing samples are initially screened to determine if DNA can be detected. If DNA is detectable, samples are then screened using regulatory sequences which detect multiple varieties (e.g., 35-S, T-Nos, BAR) to look for GM-DNA. Positive results from this initial screening are further confirmed using tests which screen for the specific genes used in the most common GM crops - the exact test used depends on the sample in question (e.g. Cry genes, EPSPS gene, Pat gene).
 For a practical description of detection methods and strategies see <http://www.identigen.com>
- ¹⁴ See JRC *Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture*, page 88
- ¹⁵ Commission Recommendation C(2003) of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming http://europa.eu.int/comm/agriculture/publi/reports/coexistence2/guide_en.pdf

¹⁶ Department for Environment, Food and Rural Affairs, Press release 311/03, 25 July 2003, DEFRA ensures precautionary action at gm oil seed rape evaluation sites
<http://www.defra.gov.uk/news/2003/030725d.htm>

¹⁷ JRC, *Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture*, page 134 http://www.jrc.cec.eu.int/download/gmcrops_coexistence.pdf

¹⁸ For a comprehensive assessment of the market implications of the new EU Food and Feed and Traceability Regulations see Greenpeace, July 2003, "The European Union's new labelling rules for genetically engineered food and feed Implications for the market of GMO and non-GMO products"
http://www.greenpeace.org/international_en/multimedia/download/1/298026/0/eu_foodfeed.pdf

¹⁹ Commission of the European Unions, Directorate-General for Agriculture Working Document Rev. 2, April 2000, Economic Impacts of Genetically Modified Crops on the Agri-Food Sector - a first review
<http://europa.eu.int/comm/agriculture/publi/gmo/fullrep/index.htm>

²⁰ BRC/FDF Technical Standard for the Supply of Identity Preserved Non-Genetically Modified Food Ingredients and Product, London 2001, available through www.brc.org.uk

²¹ Required levels of purity, minimum distances and other provisions are laid down in Annexes to the Seed Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/458/EEC, which the proposed Commission-Directive aims to amend. They can be retrieved at <http://europa.eu.int/eur-lex/en/index.html>

²² International seed purity standards are laid down in "OECD Schemes for the Varietal Certification or the Control of Seed Moving in International Trade" [C(2000)146/FINAL]
<http://www.oecd.org/dataoecd/20/19/1933955.pdf>

²³ Verordnung des Bundesministers für Land- und Forstwirtschaft über die Verunreinigung von Saatgut mit gentechnisch veränderten Organismen und die Kennzeichnung von GVO Sorten und Saatgut von GVO Sorten (Saatgut-Gentechnik-Verordnung) <http://bqbl.wzo.at/pdf/2001b478.pdf>

²⁴ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. The Directive entered into force on October 17 2002.
http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf

²⁵ For more details, general: <http://www.starlinkcorn.com/starlinkcorn.htm>, US-Environmental Protection Agency: http://www.epa.gov/pesticides/biopesticides/pips/starlink_corn_archive.htm, Legal settlement example 2003: <http://www.non-starlinkfarmerssettlement.com/> Contamination still found in shipment to Japan end of 2002: <http://www.gene.ch/genet/2003/Jan/msg00004.html> Contamination found in food aid 2002: <http://www.gene.ch/gentech/2002/Jun/msg00155.html>

²⁶ The detailed rules of "Comitology procedures" are established in Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission
http://europa.eu.int/eur-lex/pri/en/oj/dat/1999/l_184/l_18419990717en00230026.pdf