

Memorandum

On the draft Commission Directive of July 2, 2002, regarding adventitious and technically unavoidable presence of genetically modified seed in lots of non-genetically modified varieties, SANCO/1542/02 July 2002¹

Summary:

The proposed thresholds in this Directive for permitted levels of contamination² in rape (0.3%), maize, beet, tomatoes, potatoes (0.5%) and soya (0.7%) for tolerable adventitious presence of GMOs, which would not even need to be labelled, should be replaced with a single general purity standard at the technically reliable detection level of 0.1%

- 1. for reasons of environmental protection and risk management,*
- 2. to preserve freedom of choice for farmers, producers, traders and consumers,*
- 3. in consideration of practical feasibility within the entire production and processing chain of the food industry,*
- 4. in consideration of the economic impact on affected companies and costs of public administration.*

The considerations in this memorandum do not refer to the principal question whether GMOs should be used in agriculture at all or not. All facts and figures referred to are derived from documents, either prepared or commissioned by the European Union and its institutions.

Environmental protection

Currently there are no releases of genetically modified organisms (GMOs) on a commercial scale within the EU (with the sole exception of approx. 10,000 ha of Bt maize in Spain). Taking into consideration the precautionary principle and sustainable concepts for the future of agriculture, we believe that this situation should remain unchanged. General concerns about the environmental impacts of the proposed Directive have been stated by Greenpeace and other organisations³

From the environmental point of view, it should first be stated that a *general contamination of all conventional and organic seed* with GMOs, as envisaged by the draft Directive, would constitute a special form of large scale GMO releases, previously not anticipated. In addition to the commercial cultivation of genetically modified varieties on clearly identified and, where relevant, restricted areas based on authorisation under

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 The use of the standard term "contamination" is used in this context should simply as shorthand for the "adventitious or technically unavoidable presence of..."

³ Greenpeace submission: http://www.zs-l.de/gmo/downloads/greenpeace_submission.pdf, for other submissions also see http://www.zs-l.de/saveourseeds/sos_documents.html

Directive 2001/18⁴ on the deliberate release of GMOs and appropriate plant variety protection legislation, the proposed Directive would lead to widespread uncontrolled release of GMOs across all land used for production of the varieties concerned.

The monitoring of releases prescribed by Directive 2001/18 would need to be conducted on a massive scale – a scale not previously envisaged. It would be impossible to prevent or control the outcrossing of released GMOs with wild relatives where these are growing nearby. Even in nature conservation areas or other reserves, it would not be possible to guarantee that no GMOs were present. Recall measures, such as those necessary in the years 2000/2001 in America for the maize variety 'Starlink', would be presented with immense practical problems, rendering them *de facto* virtually impossible.

Finally it should be borne in mind that, in addition to authorisation in accordance with the EU Deliberate Release Directive 2001/18, a genetically modified variety must be approved under Plant Variety Protection legislation. Approval may be refused and have been refused either at national or at European level for good reasons beyond the safety issues covered by Directive 2001/18. However the proposed Directive exclusively refers to authorisation under Directive 2001/18, i.e. it would open up the possibility of contamination with varieties not approved for commercial introduction under national or European Seed legislation.

Conclusions:

- 1. The consequence of the Commission's proposal for general tolerance levels of GMO contamination of conventional and organic seed not labelled as genetically modified would be a large-scale release of GMOs which could neither be monitored nor recalled.*
- 2. This would make the legal provisions concerning the authorization of releases for limited periods of time and associated monitoring substantially more difficult if not impossible to enforce.*
- 3. The impacts of the Directive on environmental protection and nature conservation would be so serious that the only appropriate legal basis for its adoption would be the environment-related provisions of the European Treaties, and not a Commission Directive in the framework of the Common Agricultural Policy.*

Freedom of choice for consumers and producers

The principle that genetically engineered foods should only be introduced if and to a degree that protects consumers' freedom of choice, other concerns notwithstanding, is commonly held by the government and the European Union. It is also generally acknowledged that citizens expect freedom of choice not only in relation to the issue of the safety of foods for human health, but also increasingly as regards the form of production. In view of the fact that a quite overwhelming majority of our population and of all EU citizens reject GMOs in their foods, their introduction to the market would at least require to preserve the right of this majority to avoid genetic engineering. It is obvious that a guarantee of seed purity forms the indispensable precondition to this requirement.

A general contamination of seed would substantially restrict this freedom of choice for citizens. In practically all foods containing the relevant ingredients (maize, soya, rape,

⁴ 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 enters into force on October 17 2002.

beet, potatoes) a proportion of GMOs would have to be expected. This would also affect products from organic production.

The Novel Food Regulation 258/97 currently undergoing amendment ⁵ presently provides for a maximum threshold of 1% (per ingredient) of adventitious contamination with GMOs, if these are authorised within the EU. Below this threshold, the product need not be labelled as genetically modified. These thresholds were defined as a result of practical considerations relating to bulk commodities such as maize and soya imported from non-member states since 1996.

By using European ingredients and refraining from the use of the imported products in question from the USA, Canada and Argentina, currently contamination can be avoided almost completely. At least, these produce flows have not presented any risk of coming close to the threshold for labelling. The majority of food manufacturers and food traders in the European Union are currently pursuing this strategy in order to guarantee their customers that foods, and increasingly also the feedstuffs used in production of animal-based products, are free of GMOs, and so as to avoid having to label their products as genetically modified. This would no longer be possible after introduction of the draft Directive under debate here.

For all processing companies, the question of GMO contamination would be an additional risk which in many cases will necessitate continuous controls and appropriate preventive measures. These requirements would be passed on to trade intermediaries, and in turn to producers, by demanding corresponding certificates and test results. The burden of proof is fundamentally incumbent on the suppliers concerned, i.e. those wishing to avoid GMOs in their products. This is an unreasonable burden to place on members of the food industry who wish to supply products free from GMOs.

A particular problem arises for organic enterprises, where any use of GMOs is prohibited according to the Council Regulation (EC) No.1804/99 on organic production. The Regulation as it stands makes does not provide any *de minimis* thresholds regarding GMOs. Organic organisations oppose such thresholds, as they would cause considerable harm to the integrity and image of their products.

Conclusions:

- 1. Citizens' freedom of choice with regard to GMOs in their food would be severely restricted by the Directive.*
- 2. The possibilities for food processing companies and traders to refrain from the use of GMOs would be massively undermined by the Directive.*
- 3. The legal obligation to refrain from the use of GMOs in organic products would be rendered practically impossible in many cases.*

Freedom of choice for farmers

Seeds are at the root of the food production chain. Their quality essentially determines whether farmers can make reasonable efforts to guarantee that their production is free of

⁵ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, Official Journal L 043, 14/02/1997 P 0001 - 0006. Currently undergoing amendment by 1.Regulation on traceability of GMOs, GM food, feed (COM(2002) 182) 2. Regulation on genetically modified food and feed (COM(2001) 425)

GMOs and whether they will be in a position to clearly identify the causative agents of potential contamination of their products and where appropriate hold them liable for losses. It also determines whether it is possible for farmers to reproduce and further develop their own seed without risking an increase in contamination. In this respect, the prospect of contamination in the first generation emerging more strongly in the second generation cannot be ruled out. It should also be considered that any average level of contamination of particular seed lots on individual fields can deviate downward but also upward considerably.

Farmers, who practise their management not only in accordance with the current market-regulations, but also according to their own agricultural principles and convictions, cannot be expected to use seed which may contain between 30 and 70 m² GMOs per hectare without the right to know or any means of control.

Farms under organic management, which rule out the use of GMOs on principle and which are also legally obliged to do so by Council Regulation (EC) No.1804/99 on organic production, would to all intents and purposes be prevented from obtaining seed supplies on the open market. The only alternative would be a compulsory definition of specific GMO thresholds for organic products. Both options would be unacceptable, both politically and economically.

Conclusions:

- 1. The right of farmers to produce without using GMOs would be effectively voided.*
- 2. Farmers would no longer be in a position to ascertain whether and which GMOs they were producing and could no longer provide relevant guarantees to their customers and neighbours.*
- 3. The opportunity for farmers to propagate from varieties once acquired would be associated with incalculable risks and therefore severely restricted.*
- 4. Farmers practising organic agriculture would be forced to abandon either their principles or their livelihoods.*

Practical feasibility

So far contamination of seed with GMOs has not become a critical problem, although instances of such contamination have repeatedly been proven. Currently there is a 'gentlemen's agreement' in the Standing Committee on Seed that member states will tolerate contamination of up to 0.5% with varieties authorized in the EU. In Austria, a regulation on seed⁶ was passed last year which tolerates no contamination in excess of the detection threshold of 0.1%, without this having caused any problems. Italy too has announced a 'zero tolerance' policy on contamination, which is currently also being enforced in the courts. Systematic test results available from EU member states indicate that contamination in excess of 0.1% is found only in isolated cases of imported seed. The fact that the great majority of imported seed, even from the USA (where 35% of maize and 70% of soya and cotton are genetically modified), is found not to be contaminated, demonstrates the possibility of complying with strict regulations on purity.

The Commission Directive should provide effective regulation particularly in the event that GMOs are released in Europe on a commercial scale in future. In this case it can be assumed that in addition to the unlabelled contamination permitted in the seed, other

⁶ <http://www.bgbl.at/CIC/BASIS/bgblpdf/www/pdf/DDD/2001b47801>

contamination of cultivated crops is likely to occur through cross-pollination, volunteers from overwintered seed and mixing in downstream sectors.

Scientists are not yet fully in agreement on the probability, frequency and rate of the spread of outcrossing and volunteers from shed seed. Nor has enough documented experience become available. The EU's Scientific Committee on Plants gave an Opinion in March 2001⁷ which made reference to this. At the same time it presented provisional estimates of the contamination to be expected for rape, maize and sugar beet, based on the thresholds for seed proposed by the Commission at that time. On the basis of these estimates, the Committee responded with a cautious 'yes' to the Commission's question as to whether its proposed thresholds for seed ensured that the limit for adventitious contamination with GMOs defined in Commission Regulation 49/2000⁸ concerning compulsory labelling of GMOs in *foodstuffs* (and in future also *feedstuffs*) would not be exceeded.

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

	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 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 study⁶ of the co-existence of GM and non-GM crops. The final % achieved is dependent on several variables.

Table 1: Estimated average potential contamination, as estimated by the EU Scientific Committee on Plants (Source: SCP Opinion, *ibid* p.8)

It can be deduced from this estimate that the mathematical safety margin between seed contamination and product contamination assumed by the Committee is already exceedingly tight. In the case of maize, the Commission has meanwhile proposed a threshold of 0.5% instead of the original 0.3%.

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) SCIENTIFIC COMMITTEE ON PLANTS SCP/GMO-SEED-CONT/002-FINAL 13 March 2001 http://europa.eu.int/comm/food/fs/sc/scp/out93_gmo_en.pdf

⁸The labelling regulations which currently apply are based on Commission Regulation (EC) No. 49/2000 http://europa.eu.int/eur-lex/pri/de/oj/dat/2000/l_006/l_00620000111de00130014.pdf amending Council Regulation (EC) No 1139/98 http://europa.eu.int/eur-lex/pri/de/oj/dat/1998/l_159/l_15919980603de00040007.pdf

The Committee's estimate works on the assumption of compliance with good agricultural practice, which includes additional measures carried out by all farmers to separate harvested crops, control volunteers and avoid outcrossing. However, practical experience in many regions of the European Union, but also for example in the USA, counsels caution in relation to large-scale community-wide adoption of such measures, which generally involve additional effort and costs.

The Commission regularly invokes the Opinion of the Scientific Committee in determining its proposed thresholds, yet in the recent past it repeatedly called into question the reliability of the computer models and scenarios of a study by the Commission's Joint Research Centre (JRC)⁹, which the Committee in turn has used as a main reference. The Commission rightly pointed out that the scenarios involved were theoretical and had not been empirically verified.

Given this current state of knowledge, it must be assumed that the assumptions on which the Directive is based could change significantly in the light of further research and experience. Furthermore regular deviations can be expected from the average values assumed in this connection. In particular, 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, the competitive ability of GM plants, etc.). The projections of the JRC on which the Scientific Committee based its estimates serve as illustration.

Table B: Levels of adventitious presence of GM maize in non-GM grain maize production in conventional and organic agriculture with current and with recommended farming practices (50% GMOs in the region)

Farm type	Intensive maize cultivation area				Non-intensive maize cultivation area		
	Conventional France (50% of GMOs in and outside the farm)	Organic large	Organic small	Conventional Italy (50% of GMOs in and outside the farm)	Conventional (50% of GMOs in and outside the farm)	Organic large	Organic small
Farm characteristics							
Farm area	60 ha	60 ha	10 ha	50 ha	100 ha	100 ha	15 ha
Plot size	3-4 ha	3-4 ha	1 ha	8 ha	20 ha	20 ha	3 ha
Number of plots	14	14	1	3	1	1	1
Current practices							
Total rate of adventitious presence expected	2.25 % (+/- 0.6 %)	0.16 % (+/- 0.07%)	0.58 % (+/- 0.04%)	1.75 % (+/- 0.2%)	0.8 % (+/- 0.5%)	0.17 % (+/- 0.09%)	0.32 % (+/- 0.04%)
Best change of practices to meet threshold 1%	50 "days difference in flowering time + post-harvest management	Current practices	Current practices	Minimum distance 200m + post-harvest management	Post-harvest management	Current practices	Current practices
Total rate of adventitious presence expected	0.66 % (+/- 0.3 %)*			0.69% (+/- 0.3%)*	0.51 % (+/- 0.3 %)*		
Additional costs (€ / ha)	45.4 + n.d.	0	0	n.d.	n.d.	0	0

Table 2: Varying probability of contamination in maize production as estimated by the JRC with maximum level of seed contamination of 0.3% (Source: JRC *ibid* p.8)

⁹ European Commission, Joint Research Centre, Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture, May 2002. In March 2001, this study was still designated and quoted by the Committee as an unpublished "ongoing ESTO Study", and was then published in May 2002 by the Joint Research Centre of the EU:
http://www.jrc.cec.eu.int/default.asp?sldSz=our_work&sldStSz=focus_on

In all cases, setting the threshold for seed at 0.1% would enable compliance with the labelling thresholds in foods and feedstuffs without problems, and also normally allow for an adequate safety margin. As a consequence, testing and prevention procedures in subsequent stages of the production chain would be rendered superfluous or at least could be substantially reduced. By the same token, the risk to be insured against would be reduced considerably. The JRC study also made explicit comments to this effect.

Conclusions:

- 1. To date there is no adequate scientific basis on which a serious assessment can be made of the cumulative risk of contamination.*
- 2. The statements of the Scientific Committee on Seed and the EU Joint Research Centre suggest the conclusion that the proposed thresholds for seed contamination would result in contamination of foods and feedstuffs from non-genetically-modified production that inadvertently exceeded the threshold for compulsory labelling on a regular basis.*
- 3. Maintaining the level of seed purity at the reliable detection threshold of 0.1% GMO is feasible according to every expert opinion; even if the seed is produced in countries and regions in which GM crops are also produced.*
- 4. The effort required of all the companies and institutions involved, with the exception of the seed producers, would be decisively reduced by such a purity standard and the likelihood of exceeding the thresholds for foods and feedstuffs, and all the attendant consequences, could be minimized in a manner that is sustained over the long term.*

Costs

Commercial production of GMOs in combination with mandatory labelling will raise the costs of production and processing of non-genetically-modified crops concerned, in the unanimous opinion of all experts. The study by the Joint Research Centre already mentioned 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 estimated the additional production costs for maize and potato *crop production* and for *seed production* of rape, in each case for different 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 separation, testing and administration in subsequent stages of processing and trade have not yet been included; likewise the costs to the public purse, in particular in the area of inspections, agricultural information-gathering, documentation and consulting, and in the area of customs formalities. It must be assumed that an estimate of the total real costs incurred would have to be considerably higher.

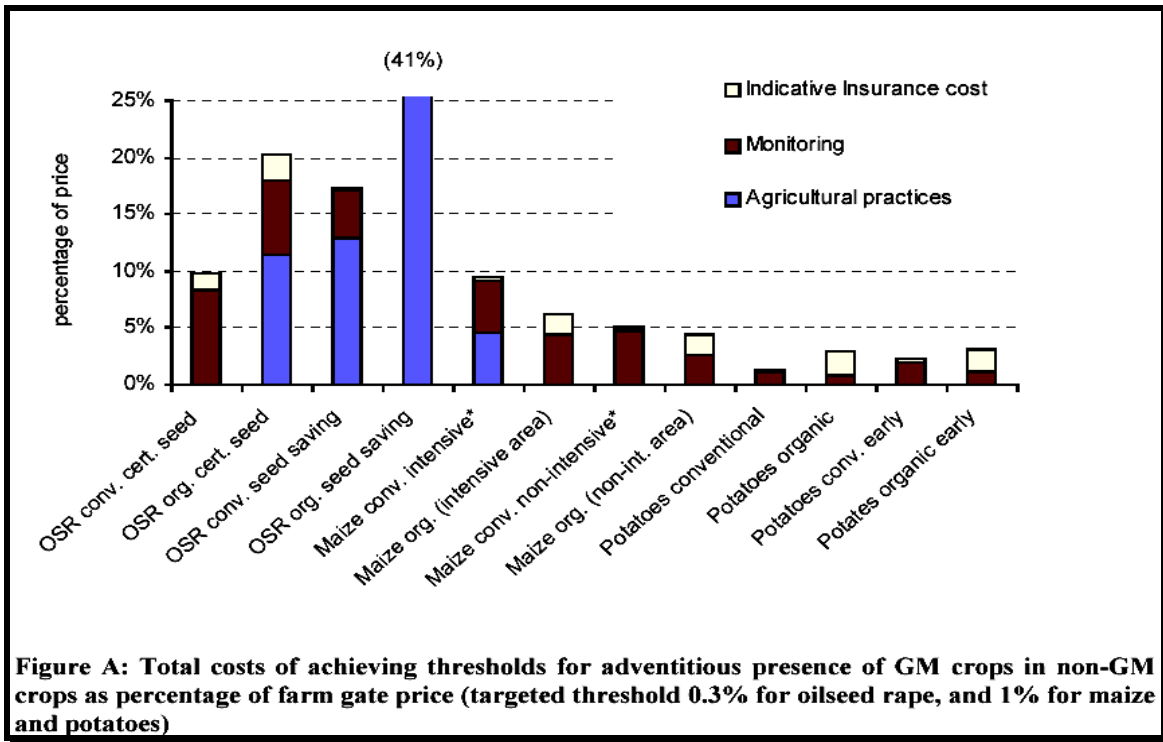


Table 3: Estimate by the EU Joint Research Centre of the additional production costs for various forms of production co-existing with GM crop production

From this survey it is clear that the additional costs of production are incurred largely due to monitoring and insurance, making a difference here of between 2 and 10 percent. The required changes in agricultural practice predominantly affect seed production (rape). Seed production of course only accounts for a small proportion of the areas under cultivation.

Seed production in rape and maize amounts to between 0.12 and 1.5 % of total production.

Comparison of annual production of seeds and crops of rape and maize within the European Union (metric tons)

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

Rape

year	Seed production EU	Crop production EU
1999	104,166	14,736,193
2000	102,873	11,706,157
2001	99,579	12,151,931

Maize

year	Seed production EU	Crop production EU
1999	667,181	73,092,073
2000	672,887	63,688,486
2001	699.673	72.967.830

As already explained, the additional costs of monitoring, certification and insurance throughout the downstream sectors would be substantially reduced if there were no

immediate danger of inadvertently exceeding the labelling threshold or food and feed. In contrast, costs increase as the thresholds for seed approach the thresholds for foods and feedstuffs. It seems no more than common sense to prevent these costs from arising at source, and not at diverse 'ends of the pipe'.

How the costs that arise are allocated within the market tends to depend on the strength of individual market players. Grocery and trade chains have so far shown little inclination in their purchasing policy to relieve their dependent suppliers of this risk. Many trade chains for example demand that suppliers provide documentation to prove that genetically engineered content does not exceed a 0.1% threshold (e.g. the technical standards of the British Retail Council). In any event they will be endeavouring to keep the risk as low as possible. A similar approach applies to the food industry.

Conclusions:

1. *The higher the permitted threshold for contamination of seed, the higher the additional costs along the entire subsequent production chain and the larger the number of companies affected.*
2. *The greater the safety margin between the threshold for seed and that for foods and feedstuffs, the less necessary and costly it will be to monitor, prevent and insure against the risk of contamination.*
3. *The smaller the number of affected companies, the easier it is to allocate additional costs incurred on the 'polluter pays' principle.*
4. *The additional costs incurred by the very few seed and propagation companies by setting the threshold at the technically reliable detection limit of 0.1% are not in any serious proportion to the additional direct and indirect costs farmers, processors, traders and the public sector would have to spend on prevention. These in turn would be reduced by a strict purity standard for conventional seed.*
5. *The present lack of clear provisions regarding liability and redress for GMO contamination under civil law harbours an economic risk for all players which is difficult to quantify.*

Schematic representation of the safety margin remaining when different threshold values apply, based on the assumptions of the Scientific Committee. The true variations could well prove to be even greater, because although the other factors are represented here as remaining static, they are likely to decrease dynamically as the threshold for seed contamination is reduced.

