



Excerpts from and comments to the European Commissions Information Note in support of the Communication from the President in association with Mrs Wallström, Mr Byrne, Mr Fischler, Mr Lamy, Mr Liikanen and Mr Busquin for an orientation debate on Genetically Modified Organisms (GMOs) and related issues

With regard to

Genetically modified seeds in non-GM varieties

An orientation debate on a diversity of GMO issues took place at the Commissions meeting on Wednesday, January 28th in Brussels and concluded with the approval of the strategy set out in this Communication. On the issue of tolerance thresholds for seeds the Commissions Communication states:

"labelling thresholds for the adventitious or technically unavoidable presence of authorised GM seeds in seeds of non-GM varieties should urgently be finalised under the environmental legislation and submitted to the vote (in the Regulatory Standing Committee). Identical thresholds should then be adopted under the seed legislation (in the Management Committee);"

In its internal Information Note in support of this Communication, which is documented (right column) on the following pages, the Commission lays out a clear concept how to establish such tolerance thresholds. In the left column "Save our Seeds" offers its comments and highly concerned conclusions.

"Save our Seeds" is a European initiative of 200.000 individual signers of a petition to keep conventional and organic seeds free of GMOs. It is also supported by more than 350 farmers, consumers and environmental organisations representing over 25 million European citizens and by many companies in the agricultural, food and retail sector. Further information about the issue of seed purity including all relevant official documents, news, positions of organisations and countries and about "Save our Seeds" can be obtained in English and German on the internet at www.saveourseeds.org

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"SAVE OUR SEEDS"
COMMENTS ON THE COMMISSIONS
INFORMATION NOTE

EUROPEAN COMMISSION:
TOLERANCE THRESHOLDS
FOR GM SEEDS IN SEEDS
OF NON-GM VARIETIES

Routine checks of seed purity in member states over recent years, including seeds imported from countries where GMOs are cultivated, have shown no contamination in most cases, and traces below 0,1% in the remaining with very few exceptions.

Full information about the GMO content of seeds should not be withheld from farmers and their customers for marketing purposes. The reality will and should in fact be shaped by the proposed legislation and not vice versa. Labelling can only be restricted by the availability and reliability of information (detection and sampling limits).

Information about the presence of GM seeds in seed lots are the prerequisite for farmers and authorities to fulfil their obligations under Directive 2001/18 and under national co-existence and liability rules and to avoid contamination of their final products above the labelling thresholds for food and feed (0,9 %).

Dir 2001/18 does not specify labelling requirements as a "general consumer information provision" as labelling is obviously required for proper risk management and monitoring. It is only the Food and Feed Regulation (EC) No 1829/2003 which provides that labelling requirements for consumer products "shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent (...) provided that this presence is adventitious or technically unavoidable."

The setting of specific, lower thresholds for organic farmers could be a serious threat for the competitiveness of this emerging market-sector and may effectively exclude them from technical and scientific progress and development in many areas of breeding.

The need for thresholds for GM seeds in seeds of non-GM varieties

Genetic modifications have been introduced in many crops worldwide and we are heavily dependent on imports of conventional seeds from third countries where GM crops are widely cultivated. The experience of recent years clearly shows that the 'adventitious' or 'technically unavoidable' presence of traces of GMOs in conventional seed lots has become largely inevitable. Currently, such seed lots have to be labelled as containing GMOs and this has created implications for their marketing.

In order to recognise this reality and facilitate the marketing of 'conventional' seed lots (including organic seeds) it has been considered necessary to establish *de minimis* thresholds below which the presence of adventitious traces of GM seeds in such seed lots does not have to be labelled.

***Legal basis under which seeds thresholds can be established*¹**

The **Seeds Directives** address in particular the question of **seed purity** and, therefore, the setting of thresholds has the purpose of **alerting farmers** to the adventitious or technically unavoidable presence of GM seeds. Thresholds under the Seeds Directives have to be established via *Management Committee procedure*. (DG SANCO chef-de-file).

Directive 2001/18/EC provides for the authorisation of GM seeds and also includes the provision to establish thresholds as a **general 'consumer' information** provision- This provision allows for thresholds to be set via a *Regulatory Committee Procedure*. (DG ENV chef-de-file)

Finally, the **organic farming regulation** allows for the setting of specific thresholds for the adventitious presence of GM seeds in organic seed lots but no threshold has so far been set via a *Regulatory Committee Procedure* (DG AGRI chef-de-file).

Therefore, the responsibility for setting de minimis thresholds for GM seeds is for the Commissioner responsible for Environment under Directive 2001/18/EC and the Commissioner responsible for Health and Consumer Protection under the seeds Directives. Co-ordination will be required to ensure consistency and coherence². The Commissioner responsible for Agriculture also has a direct interest in this matter because of its implications for co-existence and organic farming.

¹ See Opinion of the Legal Service JUR(2003) 57S6/BD of 16 October 2003

² The recently published Regulation N° 1829/2003 on **Genetically Modified Food and Feed** and Regulation N° 1830/2003 on **Traceability and Labelling** also provide for the labelling of GMOs and appropriate thresholds via a *Regulatory Committee Procedure* (DG SANCO and ENV chefs-de-file).

Regarding the scientific basis of the proposed thresholds the following should be noted:

1. The SCP actually did not confirm that the proposed seed thresholds would allow to reliably prevent contamination of the harvest below 1%. Not having made such a statement it also did not change its position regarding 0,9%.
2. The SCP did state on the other hand, that with such seed thresholds "in due course the 1% threshold set by the Commission may have to be revised."
3. The calculations of the SCP for oilseed rape, maize and beet resulted in minimal safety margins of only 0,09 to 0,38% below the 0,9% margin and did not take into account additional contamination sources during processing of the farm products. Already standard deviations from the mean contamination factors taken into account by the SCP could result in contamination levels above 0,9%.
4. The SCP calculations have since been severely questioned by newer scientific studies and leading members of the SCP have confirmed that their assumptions may have to be revised, notably regarding the distances of outcrossing and the persistence of seed in the soil.
5. The Commission has since changed the proposed threshold in maize from 0,3% to 0,5%.
6. The factors for self-pollinating and cross-pollinating crops mentioned in the footnote have not been endorsed or mentioned by the scientists and do not reflect the realities of the different crops and their behaviour.
7. The SCP "is also firmly of the opinion that, in addition to the thresholds of 0.3% or 0.5% defined for seed used to produce the crop, farm management and commercial production practices will influence the ability to achieve a 1% threshold in food and feed". Neither the SCP nor the Commission have properly specified, which appropriate farm management and commercial production practices would be required to achieve conditions under which the proposed seed-thresholds would guarantee to remain below the set food and feed labelling thresholds. Such conditions would require not only scientific but also practical and technical scrutiny under realistic field conditions. However, they are fundamental assumptions upon which the SCP based its opinion.
8. Not having been asked by the Commission the SCP did not answer questions regarding the environmental risk management implications of the proposed thresholds. However, it is obvious that such thresholds would inter alia
 - Make recalls and withdrawals of GMOs in cases of emergency or expiry of the approval practically impossible (up to 0,5% in all seeds of a crop)
 - Drastically impede the post market monitoring as required in Directive 2001/18
 - Increase the probability of "gene stacking" (crossing of different GMOs) and emergence of unapproved re-combinations of GM crops.
 - Have severe implications on farm saved seeds, in which GM contamination could accumulate

What has been done so far?

DG SANCO has finalised a proposal to amend the seeds Directives to include thresholds for adventitious traces of GM seeds.

The threshold values were based on the opinion of the Scientific Committee on Plants (SCP), adopted in March 2001, in the context of two values (0.3 and 0.5%) initially proposed by DG SANCO.

Both thresholds were originally considered in light of the 1% threshold which was established for the adventitious presence of authorised GM material in food and food products. The SCP reconfirmed its initial opinion in January 2003 given the lower 0.9% threshold established under new Regulation on GM food and feed.

What did the Scientific Committee on Plants recommend?

DG SANCO's question to the SCP on the thresholds was:

As a threshold of 1% was established for the adventitious presence of (authorised) genetically modified material in food and food ingredients ..., the Commission is considering to propose the following thresholds³ for the adventitious presence of GM seeds covered by an authorisation under part C of Directive 90/220/EEC:

- 0.3% in the case of cross-pollinating crops
- 0.5% in the case of self-pollinating crops and vegetatively propagating crops.

Does the Committee find any error or difficulty in this reasoning? If so, what other threshold(s) would be justified?

In its response, the SCP opinion provided the scientific background, based on 3 examples (oilseed rape, maize and sugar beet), to enable decision makers to decide upon seed thresholds that would allow farmers to produce crops not subject to labelling, assuming that appropriate farm management and commercial production practices are implemented. In its opinion, the SCP pointed out that the thresholds proposed by DG SANCO at that time (0.3% for cross pollinating and 0.5% for self pollinating species) would only be achieved **under ideal conditions**. The SCP opinion continues "Achieving the 0.3 and 0.5% thresholds will become increasingly difficult as GM crops in Europe increases".

How the proposed thresholds have been reached?

DG SANCO proposal was based on scientific elements contained in the SCP opinion and on the thresholds confirmed by the SCP for self-pollinating species and vegetatively propagating species (0.5%) and for cross-pollinating species (0.3%). As a result, DG SANCO proposed in two cases (maize and soya) slightly increased thresholds which on the basis of the science provided by the SCP opinion, would still enable farmers to produce non-GM crops and ensure that the labelling threshold in food or feed is met.

Have the proposed thresholds been contested?

A number of Member States, certain EP committees and NGOs raised concerns about the complex interplay between the above mentioned legislations and furthermore criticised, as a matter of principle, the (high) level of the proposed thresholds for seeds. In particular,

³ These thresholds were proposed by the Commission on experience in seed production as regards multiplication of seed impurities (multiplication of a factor 2 in case of self-pollinating crops: 0.5% proposed for seeds in relation to the 1% target, multiplication of a factor 3 in case of cross-pollinating crops: 0.3% proposed for seeds, in relation with the 1% target)..

So far four member states made statements in favour of the proposed thresholds four others demanded labelling at the practical detection level of 0,1%. The voting majority of member states has no position yet.

According to the regulatory procedure the Commissions proposal will be forwarded to the Council of Ministers, should the Regulatory Committee not approve it with qualified majority. Should the Council not reach an agreement on the issue with a qualified majority within 90 days the Commission will be free to legally implement its initial proposal.

Conclusions:

1. The Commissioners agreement indicates no intention to seek additional scientific advice and take into consideration newer scientific findings.
2. The emphasis that its policy change was "not a technical issue" indicates that the Commissioners do not intend to substantially change the proposed labelling thresholds.
3. The Commission approach leaves no room for the participation of the European Parliament in this matter.
4. Despite massive criticism from farmers, food processors, retailers, consumer and environmental organisations the Commission does not indicate any willingness to take into account the practical and fundamental problems along the production and food chain.
5. The Commission does not mention the massive financial burden these arbitrary labelling thresholds for seeds would impose on all farmers, food processors and retailers, especially those who want to produce without GMOs. These include additional testing requirements and control measures - in the harvest instead of the seeds much larger quantities are concerned - further down the production chain. They also entail legal risks and uncertainties regarding liabilities, for which no insurance coverage is available at present. They can finally include exorbitant measures and costs in case a recall of a certain GMO would become necessary.
6. The setting of labelling thresholds above the practical detection limit would effectively allow seed companies to withhold from their customers and the authorities information they have (and are legally obliged to generate) about the GMO content of their products. The only reason given for this unusual approach is "the marketability" of certain seeds, contaminated with GM crops.
7. Without full information about the GM content of their seeds conventional and organic farmers will no longer be able to guarantee non-GM production. Hence the proposed labelling thresholds for seeds would undermine the concept of free choice and self determination of farmers and consumers in Europe.

?? While certain Member States support the proposed thresholds, others plead for lower thresholds (closer to the detection limit 0.1%). It therefore seems probable that neither these thresholds nor thresholds close to the detection limit on 0.1% would receive a qualified majority when presented to the Regulatory Committee;

?? The seeds thresholds issue has recently been addressed in the own initiative report of the European Parliament Agriculture Committee on 2 December 2003, discussed at the EP Plenary of 17 December⁴.

The legal issue

Last October, whilst DG SANCO proposal on the matter was about to be adopted, the Legal Service⁵ advised that labelling thresholds set under the seed directives would not provide exemption from the labelling requirements of Article 21(1) of Directive 2001/18/EC, unless similar thresholds are established under Article 21(2) of the Directive. The Legal Service offered several options to address the legal issue.

The strategy was agreed by all involved services at this time was that labelling thresholds would first be established under the Directive 2001/18/EC by DG ENV (regulatory committee) and that identical thresholds would then be adopted under the seed directives managed by DG SANCO. The policy change was due to a legal issue and not to a technical issue but also considered the procedures for adoption under each instrument.

State of play

This matter has been intensively discussed in the Biotechnology Steering Committee and in *ad-hoc* meetings at service and Cabinets level.

Finally, in an ad-hoc meeting on 13 January, the concerned Commissioners agreed that a Commission proposal will be finalised as soon as possible under Directive 2001/18 -based on the opinion of the 2001 Scientific Committee of Plants. Identical thresholds will then .be adopted under the seed Directives.

⁴ The adopted report says that a limit value for the labelling of GMO impurities in seeds should be set "at the technically reliable detection threshold". Moreover, it refers to the need to take into account scientific assessments as regards practical applicability.

⁵ Opinion of the Legal Service ;JUR(2003) 5786/BD of 16 October 2