

European Seed Association



Contribution

to

**Draft Commission Decision (EC) No.../..
establishing minimum thresholds for adventitious or
technically unavoidable traces of genetically modified
seeds in other products**

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With this Position Paper, ESA reacts to the current inter-service consultation in the European Commission on a new joint DG ENVI / DG AGRI proposal for the setting of thresholds for the adventitious presence of GMOs in other products in the framework of Directive 2001/18/EC.

General

ESA welcomes that the Commission is now pursuing this important and urgent matter for the EU seed industry with its new draft proposal.

ESA urges the Commission to amend its draft proposal by deleting Article 4) and providing for a threshold level of 0.5% for maize in the Annex.

We also re-state our position that the first step such an amended proposal will present must be taken without any unnecessary delay.

Voluntary labelling provisions in/by Member States

ESA opposes any provision allowing for voluntary labelling systems to be set up by Member States or at any other regional level.

Such provisions run contrary to the principles of the Internal Market (Art. 3 c of the Treaty), to Art. 22 of Directive 2001/18/EC and are inconsistent with the existing EU legislation on traceability and labelling of GMOs. They will also limit the future contractual possibilities of seed producers and farmers / growers without bringing any benefits to either one.

Additional national or regional labelling systems or requirements as proposed in Article 4 of the current draft will constitute a hindrance to the free circulation of seed in the Internal Market. This hindrance will become the more unbearable for seed companies and farmers the more different labelling provisions and requirements are set.

Labelling and traceability systems that are based on specific national legislation and involve respective competent authorities and lead to or recommend the labelling of GM admixtures at concrete levels below the

ESA

23, Rue de Luxembourg ; 1000 Brussels ; Belgium
Tel. +32-2-7432860 ; Fax +32-2-7432869 ; e-mail: secretariat@euroseeds.org
www.euroseeds.org

threshold(s) set by EU legislation will counteract the spirit of EU Regulations 1829/2003 and 1830/2003 by automatically triggering traceability and labelling requirements all the way down the chain.

Proposed threshold value for maize seed

ESA strongly opposes the lowering of the threshold level from 0.5% (as proposed in 1542/2002/SANCO) to 0.3% as now proposed by DG ENVI and DG AGRI.

Based on practical experience and research, ESA is convinced that a maize threshold level of 0.3% is economically unsustainable and poses unnecessary additional costs on seed producers, farmers and consumers in the EU and is therefore an infringement of the general principle of proportionality laid down in Art. 5, para 3 of the Treaty.

We are also convinced that the findings of the Scientific Committee on Plants of 7.3.2001 clearly show that a threshold of 0.5% is compatible with the labelling threshold set for GM food and feed.

Further action needed

We re-state our position that the draft proposal may be regarded only as a first step towards a consistent EU policy and legislation, including the setting of thresholds, for the adventitious and technically unavoidable presence of all GMOs that may be present in conventional as well as GM seed. Due to the international nature of variety development, seed production and seed trade as well as because of biological realities in farming and practice in trade, other events than those covered by the proposal may adventitiously be present in seed to be used in the European Union. We call upon the Commission to pursue this matter with the necessary urgency.

Conclusion

ESA European Seed Association

- welcomes the Commission's intention to proceed in its attempts to regulate this first part of GM events that may adventitiously be present in conventional seed and urges the Commission to propose the necessary subsequent legislation at the earliest possible moment;
- rejects the idea to provide the legal option for voluntary national labelling and traceability requirements as we consider these to be contradictory to Internal Market provisions and counterproductive as regards customer and consumer information and choice;
- calls upon the Commission to revert to a threshold level of 0.5% for maize as contained in its earlier proposal as a level of 0.3% as contained in the recent draft is economically unsustainable and will unnecessarily harm the competitiveness of the European seed industry and its customers, the European farming community.

Annex: Background Document

Background Document
**to the ESA Contribution to the Commission's draft proposal for the
setting of thresholds for AP of GMOs in other products**

I. General

ESA principally welcomes the fact the Commission –after the change of responsibilities from DG SANCO to DG ENVI in October 2003- is pursuing this important and urgent matter with a concrete draft proposal.

a) Events covered by the draft proposal - general

We re-state our position that this draft proposal may be regarded only as a first step in a consistent EU policy and legislation, including the setting of thresholds, for the adventitious and technically unavoidable presence of all GMOs that potentially may be present in conventional as well as GM seed.

Such legislation must set thresholds for the AP of

- all events authorised under part C of Directive 2001/18/EC, not only those authorised for cultivation
- all events authorised for deliberate release under Directive 2001/18/EC, part B, i.e. for field trials / experimental releases
- events that have been authorised by third countries under similar legislation (including the respective risk assessments) than in the EU

as due to the international nature of variety development, seed production and seed trade as well as because of biological realities in farming and practice in trade, all the events listed above may adventitiously be present in seed to be used in the European Union.

We quote the Scientific Committee on Seeds Opinion of 07.03.2001, p. 13, where it states:

“From experience of research on unintentional seed mixing, of gene-flow, and from long experience of commercial seed production it is clear that a zero level of unauthorised GM seed is unobtainable in practice. Field grown crops are always subject to unintended pollen and seeds from various sources”.

The Scientific Committee also states that “A zero level would have severe consequences for part B GM field releases, for biosafety research and for evaluation of new GM plant varieties”.

We remind the Commission of its own respective findings in its recent progress report on the implementation of Biotech Action Plan where it had to acknowledge that research into plant biotechnology including practical field trials has practically grind to a standstill in the European Union.

b) Events covered by the draft proposal – pipeline events

ESA takes the ‘whereas’ clause no. 9 in the current draft proposal as an indication that the Commission is aware that at least a provision comparable to the one contained in Regulation EU 2003/1829 covering the so-called “pipeline events”, i.e. events that have already benefited from a favourable scientific risk assessment but that are not yet authorised due to the political authorisation moratorium, should be considered.

We again point out that, not least in view of the encountered uncertainties of the political authorisation process, a transitional period is required as a general and unlimited provision to assure the smooth transition of GMOs from the first trial stage under part B to the final authorisation for cultivation under part C of EU Directive 2001/18.

c) Crops covered by the draft proposal

ESA would welcome clarification from the Commission why the scope of the current draft proposal is limited to this small number of species. We take it that this limitation could be due to the fact that -at this moment- no GM authorisations for cultivation have been granted or requested for other species.

Still, we are of the opinion that this proves ESA’s point that further legislation is and will be required with the further development of the technology and its use.

ESA reminds the Commission that e.g. GM soya is currently grown at levels of up to 80% – 90% of the overall soya production in many of the major soya seed and crop producing countries.

As Europe is highly dependant on seed imports for the production of a number of crops, including soya, we urge the Commission to fulfil its obligation to provide the necessary complete, consistent and proportional legislative environment required by seed industry and farmers to exercise their freedom to operate.

II. Voluntary labelling provisions in/by Member States

ESA opposes any provision allowing for voluntary labelling systems to be set up by Member States or any other regional level.

We are convinced that such provisions for national/regional systems run contrary to the principle of the Internal Market and are inconsistent with the existing EU legislation. At the same time, they will limit the future contractual possibilities of seed producers and farmers / growers without bringing any benefits to the one or the other.

a) Internal Market

The existing EU legislation and system of regulation covering the marketing of seed in the EU constitutes the Internal Market for seed. Seed may move freely between Member States provided the EU rules and regulations are observed.

This achievement has also led to a situation where farmers are able to choose from an ever-increasing number of specific varieties according to their needs and markets. This has helped to increase the productivity of European farmers and to safeguard their competitiveness.

Official labels required and regulated by EU legislation allow for easy identification of seed and constitute a mutually agreed passport for seed travelling in international / intra-Community trade.

Any additional national or regional labelling system or requirement as proposed in Article 4 of the current Commission draft will undoubtedly constitute a hindrance to the free circulation of seed in the Internal Market. Obviously, this hindrance will become the more unbearable for seed companies as well as for farmers the more and potentially very different labelling provisions or requirements are set up by Member States.

ESA is of the opinion that the Internal Market for Seed must not be hampered by unnecessary national legislation regarding the labelling of seed as this labelling as well as exemptions from it will already be subject to clear and uniform respective EU legislation.

b) Inconsistency with existing EU legislation

EU Regulation 1829/2003 and 1830/2003 provide for exemptions from the general obligation to trace and label food and feed products produced from or containing GMOs in case

- the presence is below a set threshold (0.9% and 0.5% respectively)
- the presence is adventitious and technically unavoidable
- the operator can submit evidence satisfying the competent authorities that appropriate steps have been taken to avoid the presence of such material

ESA is of the opinion that labelling (and traceability) systems that are based on specific national legislation and involve respective competent authorities and that would lead to or recommend the labelling of GM admixtures at concrete levels below the threshold(s) set by EU legislation will automatically trigger the traceability and labelling requirements all the way down the chain. Once the concrete presence of a certain GM content –even if below the EU threshold- is stated on an official or officially recognized label, subsequent operators may not claim that the presence of this GM content in his product is adventitious or technically unavoidable.

c) Contractual agreements of private parties

ESA is of the opinion that private parties are free to conclude contractual agreements that might also involve specific seed quality requirements. Such agreements must not contradict EU legislation but should be in line with it.

Specific product qualities may only result in extra financial benefits or a premium for the product(s) throughout the chain if they are not already prescribed by legislation anyway and with that constitute a general product quality requirement.

III. Proposed threshold values

ESA shares the opinion of the Scientific Committee on Seeds of March 2001 that with the proposed threshold levels of 0.3% and 0.5% (depending on the crop) contained already in the first Commission draft 1542/2001/SANCO, the threshold laid down in Regulation (EC) 1829/2003 may be achieved, but

- that the proposed thresholds for seed will “only be achieved under ideal seed production conditions”,
- that “achieving the 0.3% and 0.5% thresholds will become increasingly difficult as GM crop production increases in Europe” and
- that “In due course the 1% threshold set by the Commission may have to be revised”

[quotes from the Opinion of the Scientific Committee on Plants of 07.03.2001]

ESA maintains its position that the threshold level proposed for oilseed rape (0.3%) will prove to be practically and economically unachievable once GM production of this crop has reached a certain percentage of overall production in Europe.

As regards maize, ESA strongly opposes the lowering of the threshold level from 0.5% (as proposed in 1542/2002/SANCO) to 0.3% as now proposed by DG ENVI and DG AGRI.

We are convinced that on the basis of the economics of current seed production, seed use and farming in Europe, this lower level will result in extremely high discard levels that pose unnecessary additional costs and burdens on seed producers, farmers and finally consumers in the EU.

ESA draws attention to the Commission’s motivation that threshold values ‘should be scientifically sounded, operational, such that they can be met by appropriate management practices, as well as enforceable’ [quoted from draft Commission Decision, Whereas 4)]. Based on practical experience and research and in particular pointing once again to a recent study on the cost effects of different threshold levels for AP in maize carried out in a GM environment¹, ESA is convinced that a threshold level of 0.3% for maize is economically unsustainable for EU seed production and EU farmers.

We are also convinced that the findings of the Scientific Committee on Plants of 7.3.2001 clearly show that a threshold of 0.5% is compatible with the

¹ Nicholas Kalaitzandonakes: “The Economics of Regulatory Standards: the case of GMO Purity Thresholds”; EMAC Economics and Management of Agribiotechnology Center; Working Paper 21-03; University of Missouri-Columbia; December 2003

labelling threshold set for GM food and feed [v. Opinion of the Scientific Committee on Plants of 7.3.2001, p.5].

IV. Facts and Figures

ESA once again draws the Commission's attention to a number of facts regarding maize seed production and the potential economic consequences for the competitiveness for the EU based seed industry as well as ultimately, European farmers and consumers.

- **Development of global acreage of GMOs**

Naturally, the development of GM seed and crop production worldwide is an important factor when analysing the practical possibilities and consequences for the setting of thresholds for the AP of GMOs in conventional products.

Since its introduction, GM crop production has grown at impressive and consistently two digit rates. Today (2003), approx. 70 million hectares of GM crops are grown worldwide with an increase of 15% (= 9 million ha) between 2002 and 2003.

Conservative predictions estimate a growth to 100 million ha worldwide over the coming 5 years.

Globally, of the 140 million ha on which maize is grown, some 11% is GM.

In the EU, so far commercial GM cultivation is limited to GM maize grown in Spain on an area of some 25.000 ha. It should however be noted that prospective EU Member States Romania and Bulgaria both commercially grow GM crops with Romania exceeding 50.000 ha of production in 2003.

[Source ISAAA: Preview Global Status of Transgenic Crops 2003]

- **Structure of Maize seed production**

	FRANCE (=EU)*	USA	Hungary
Multiplication area ha	50.000	300.000	30.000
No. of companies	30	100	11
No. of varieties produced	1.200	>1.000	400
Average production area per variety (ha)	40	300	75
Average seed production area per farmer (ha)	12	50 - 200	215
Average size of seed production fields (ha)	3	50	43

* France accounts for more than 80% of the EU 15 maize seed production and therefore may be used as model representing the EU 15 in total.

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The figures have been assembled from seed associations and individual companies and seed producers. They may be contested as to their absolute accuracy. Still, they do show a clear and true picture of the differences of seed production in the current EU 15, the largest producer in the world, the USA, and the by far largest seed producer of the new EU Members States, Hungary. It is obvious, that the seed production area per variety is approximately 10 times bigger in the main competing countries USA and Hungary than in the current EU

- **Maize Seed imports into EU**

The current EU maize seed production does not satisfy the EU's maize seed demand. On average, around 30% of the maize seed used in the EU originates from imports. These seed imports largely come from the USA, Argentina, Chile and Hungary. Most of these countries have extensive GM maize seed and crop production shares (v. table).

GM shares in seed and crop production in selected exporting countries

	% GM of total maize crop production	% GM of total maize seed production
USA	45	45
Argentina	40	40
Chile	0 ²	50

- **Maize Seed Purity Levels in France 1992 - 2002**

French maize seed production represents approximately 80% of the total EU 15 maize seed production. As a classical export oriented economic activity with competition from other large scale seed producers from outside the EU, its quality has been closely monitored and documented for many years both by the industry itself as well as official seed certification authorities.

The following table shows the total seed impurities (I = total seed impurity levels) for the different years (Y) for certified seed of commercial hybrids.

Total seed impurities in maize

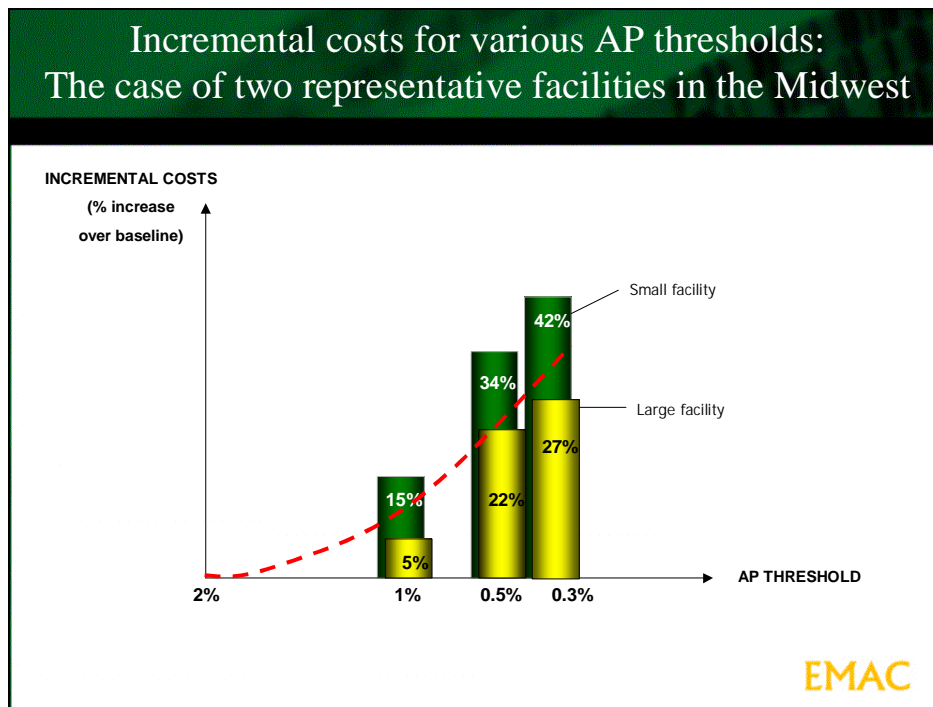
Y	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
I	1.15	0.81	0.68	0.68	1.07	1.01	0.84	0.53	0.64	0.74	0.56

With that, the average level of impurities reached over 11 years is 0.80%.

² Officially, Chile does not grow GM maize. It is however known that farmers are increasingly using GM seed imported from other South American countries. Latest assumptions are that approx. >30% of the maize grown in Chile is GM maize.

- **Key findings of a recent study on costs of AP levels in maize seed**

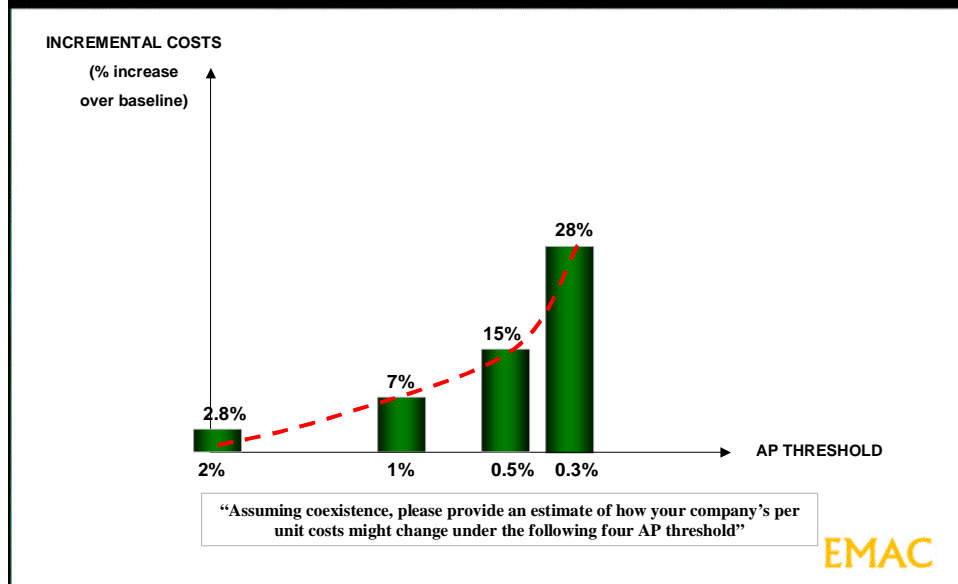
The following presentation shows some of the findings of a recent study carried out in the US, i.e. under co-existence conditions of GM and non GM seed and crop production*.



The findings clearly show that costs rise exponentially with a lowering of thresholds levels and that smaller facilities will experience substantially higher costs than larger ones.

* Nicholas Kalaitzandonakes: "The Economics of Regulatory Standards: the case of GMO Purity Thresholds"; EMAC Economics and Management of Agribiotechnology Center; Working Paper 21-03; University of Missouri-Columbia; December 2003

Incremental costs for various AP thresholds: *Results from the industry survey*



Comparing the results from the study with the results of an industry survey (questionnaire), it is interesting to note that companies even underestimated the potential additional costs caused by different threshold levels.

Regional variation in projected compliance costs

Results from the industry survey

		2%	1%	0.50%	0.30%
European Union	Average	1.67	8.00	16.67	30.83
	SD	2.25	5.62	8.16	13.93
North America	Average	2.80	6.32	13.76	25.10
	SD	3.59	6.03	8.76	18.32
South America	Average	0	4.60	10.40	24.00
	SD	0	2.19	6.77	8.22

"Assuming coexistence, please provide an estimate of how your company's per unit costs might change under the following four AP threshold"

EMAC

The overview shows that compliance costs will be substantially higher in the EU than in other major production areas of the world. This disadvantage is mainly based on the different structures of production as pointed out on page 7 (Structure of Maize seed production in Europe, the USA and Hungary and third countries).