

Submission of Europa-Bio

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Lack of Rules leads to Disruption in the Seed Trade in the Member States

The lack of clarity and lack of rules allowing for adventitious presence of GMO's in seed production and marketing is leading to a high degree of commercial and operational disruption in the Member States.

- There is a complete absence of clear and predictable rules as to how adventitious presence should be handled.
- Seed companies and farmers are thus likely to suffer loss of reputation and in cases of dispute severe financial consequences. In dealing with the current confusion, very considerable costs are already being expended by members of the seed industry.
- There is a very considerable confusion about adventitious presence of GM seed in non-GM varieties with resulting disruption to seed operations, seed distribution and the commercial chain.
- In some cases, material in international trade has been affected.
- Interest groups are raising their own issues in the absence of clear rules.

As seed is the beginning of the food production chain, gaining an acceptable and practicable solution to the issue of adventitious presence at this level, i.e. in certified seeds, must be the first priority.

Background

- Seed variety purity is traditionally based on morphological characteristics determined visually.
- The variety purity levels are set differently for each crop species based on the biological characteristics of the crop species i.e. different species behave differently, especially with respect to their reproductive biology, in the environment.
- Adventitious presence of GM material, on the other hand, will presumably be assayed using modern molecular detection methodologies, and will enable the detection of the presence of modified genetic material even though this results in no visually discernible morphological change in the plants. We may anticipate higher levels of GM impurities because of these new and very sensitive detection methodologies.
- Current thresholds set for crop variety purity can therefore only act as guiding values in determining thresholds for the adventitious presence of GM material.
- Seed production is a global activity, and agricultural systems in certain geographic regions are much better able to provide the currently legislated isolation of a seed crop from its relatives than other regions. In Europe, availability of suitable growing conditions is more limited than for instance the vast plains of north and south America. Setting unrealistic

thresholds for the adventitious presence of GM seed in non-GM seed will likely penalise the EU's seed industry in favour of foreign seed producers.

- Likewise, setting threshold levels that are exceedingly onerous will discriminate against the many small seed producing companies in Europe while favouring the fewer larger companies able to operate globally. The setting of overly onerous thresholds for the adventitious presence of GM in non-GM seed will encourage further consolidation in the plant breeding and seed production sector.
- Cost penalties will be inversely and exponentially proportional to any threshold level which may be set. Low thresholds will be attainable only at high additional cost, and there will be threshold below which any extra cost will provide no further reduction in AP. In addition, extra costs will be incurred as operators scale up production to cover potential required discard levels.
- It is already acknowledged that an adventitious presence threshold of zero is unattainable (Opinion: Scientific Committee on Plants 9 March 2001), but it should also be recognised that additional expenditures will achieve no added security below a certain threshold level.
- High rates of discard of seed not meeting the threshold standards will escalate costs, and some operators may very well choose not to attempt seed production because of the added risk of failure in achieving these levels.

I. Practical Thresholds Levels⁽¹⁾:

In considering the above elements, and discussions with the European Commission's DG SANCO Seed Unit, we consider the following as stringent but workable threshold levels for adventitious presence (including non-EU approved events) of GM seed in certified seed of the major crops. In some cases, these values are driven by future commercialisations.

- Maize - 1%
- Soybeans - 1%
- Sugar Beet - 1.5% (To date there is very limited experience in field production of GM sugar beet – this figure is suggested as an interim measure)
- Open pollinated Oil Seed Rape - 2%
- Hybrid Oil Seed Rape⁽²⁾ – 5%
- Tomato – 1%
- Small grained cereals 1% (To date there is very limited experience in field production of GM cereals – this figure is suggested as an interim measure)

Other crops will follow as indicative data is generated.

(1) Variation in seed production years: A key fact in attaining variety purity, and consequently in setting thresholds for adventitious presence thresholds, is the yearly variation in variety purity resulting from variation in climate, wind etc. experienced during the pollination period. To illustrate this we append in an annex information from SOC in France with respect to variety purity of conventional maize hybrids. The SOC data suggests that, should the threshold be set too low, in some years there may be severe shortages of seed.

It is very important to recognise that this data has been generated using the methodology of visual observation of morphological characteristics and therefore the experience is not directly applicable to more modern laboratory molecular techniques.

(2) *For reasons of plant biology, production of hybrid oilseed rape poses additional problems in achieving high levels of variety purity. Detailed technical and biological input data will be provided separately.*

II. Cost and Practical Contributors to Threshold Setting:

Key elements contributing to the cost and practicality of setting individual thresholds for GM material in non-GM seed on a crop by crop basis are:

- Discard rates (destruction) of seed produced that does not achieve the required threshold levels;
- Increase of production levels to cover probable discard rates.
- The need to use expensive testing methodologies;
- The need for standardised sampling methods and validation of reliable molecular testing methods;
- The availability of the necessary land base to achieve the required isolation distances; and
- The logistics involved in developing a tighter seed production handling and distribution chain.

The Table Below provides an indication of the cost impact of each of these elements for the production of hybrid maize seed:

Table: Cost contributors to Threshold Levels

Cost Element	Median cost impact for suggested threshold⁽¹⁾
Discard Rates	High
Increased Production Levels	High
Testing	Medium
Standardised sampling/validation	Low
Logistics	Medium
Land Base availability	Very high

(1) *The SOC data on maize indicates that discard levels are likely to vary on a year by year basis, and suggest that in some years there will be severe shortages of seed of conventional varieties should the threshold levels be set too low.*

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