

Adventitious Presence of GM Seeds in Conventional Seeds

**A Background Report to
Inform Good Policy-making
in the EU**

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Produced by

Executive summary

1. In the European Union, **there are no EU-wide threshold levels for the inadvertent (adventitious) presence (AP) of GM seeds in batches of conventional seeds**. The lack of an EU threshold means that operators are required to label as GM, any seed batch if it contains any trace of GMOs approved for cultivation in the EU. In cases where traces of not yet authorized GM seeds are found in batches of conventional seeds, the batches cannot be sold in the EU. If they are found after planting, crops are destroyed.
2. This problem **affects the entire seed sector** including smaller and larger operators that produces only non-GM seeds are increasingly running into problems.
3. There is **unanimous political support that thresholds are needed**, from the public and private sectors. This includes European Ministers who have unanimously requested a solution for many years. The European Commission has recognized this for over a decade, and has undertaken four attempts to set thresholds. Each has failed for political reasons. The European seed industry has asked for solutions levels since 1999. European farmers have requested this for over a decade.
4. Two trends make the **need for a threshold or common testing standards more acute**. These trends are the rapidly increasing presence of GM seeds globally and the increasing trade of seeds globally.
5. These trends are at the root of **four negative effects**: extremely costly incidents, increasing operational costs for seed companies and farmers, a reduction in European agricultural competitiveness, and the reactions to the lack of EU solution by Member States, namely the application of national tolerance approaches. This last development in particular means that there is now **no longer a fully functional EU Single Market for seeds**.
6. Preliminary **legal insights** suggest that the lack of action to set thresholds to protect the Single Market may be unlawful. The setting of a GM feed testing protocol has set a legal and political precedent that makes it legally more imperative to apply this principle to seeds.
7. **Political action is needed to restore of the EU Single Market in seed**. Specifically, the European Commission and Member States must move to set:
 - Clear and practicable technical testing protocols for detecting the presence of GM seeds in conventional batches, and,
 - Agree and set labelling thresholds for adventitious presence of approved GM seed in conventional seed, and in so doing eliminate the diverging national approaches.

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1. The seed sector

Seed makes food, feed and biological raw material for industrial uses. The global seed trade is valued at around €45 billion, of which the internationally traded part is about €10 billion, and is rapidly increasing. The seed sector is a very research and development intensive sector with long product development cycles. Seeds are very high value products (add example of average price for a batch of tomato or other seed).

A seed contains all the genetic information that determines the final plant's appearance (size, shape, colour), growth performance (yield), and its nutritional (sugar or fatty acid composition) or technical (industry oils or biofuels) values. While environmental conditions (sunlight, water, nutrients and quality of soil) and production techniques are influential too, it is the genetic information contained in the seed that determines the plant's potential.

Seeds are the single most important factor in increasing crop yields and in raising the quantity and quality of agricultural production.

To supply the needs of an expanding agriculture for quality seeds, a sophisticated plant breeding industry has emerged over the past century. Its contribution to farming has been fundamental in the development of the modern industrial and service societies of today. To meet different growing conditions in different regions, and achieve the desired qualities for different end uses of the harvest, plant breeders have developed large numbers of specific varieties of the same species.

Breeding these varieties, and generating large volumes of their seed for sale to farmers, often takes place in exactly the same areas as the final commercial farm production – for the obvious reason that this allows the best match between a variety and specific growing conditions.

The past century has seen the emergence of a wide range of quality standards and controls, to ensure that farmers are fully informed about the seed they purchase. Harmonised rules have permitted a dramatic increase in this international seed exchange worldwide and in particular in Europe, where cross-border trade in seeds is the norm in the EU's Common Market.

Many seed firms operate internationally. Even medium-size or smaller companies often operate R&D and breeding stations around the world. Different geographic locations allow for experimentation with germplasm base under different conditions. Production and processing operations are internationalized and seed companies make use of counter-seasonal production locations in the southern hemisphere in order to speed up product development and shorten innovation cycles. Most companies ship seed (including commercial, foundation or research seed) from one country to another at some time. Shipments must meet complex seed health standards and other requirements.

INSERT BASIC FACTS ABOUT THE EU SEED INDUSTRY – EMPHASIS ON SMEs

2. What is adventitious presence?

“Adventitious presence” (AP) or “low level presence” refers to the unintentional and incidental commingling of trace amounts of one type of seed, grain or food product with another. Adventitious presence is an unavoidable reality of plant biology, seed production and the distribution of commodity crops.

While adventitious presence can be minimized, as a practical matter it cannot be eliminated entirely. This applies to all crops, seeds, grains and even food. Adventitious presence in seed occurs through unintended mixing during sowing, harvesting, and processing, or through outcrossing with pollen from nearby fields. As a result, allowances for adventitious presence have been recognized in laws, regulations and standards that establish allowances for these materials. Since plant breeding, seed production and commercial farming are all conducted in the same open farming environment, it is equally impossible to achieve 100% purity in any seed. Depending on species and crop type, there may be cross pollination of the seed bearing plants with pollen from different varieties outside of the seed production area, and also from mixing during the harvesting, cleaning and packaging operations.

Low impurities in seed of any crop have therefore always been accepted and the EU’s seed legislation defines acceptable and economically practicable levels for such AP. In conventional seed breeding, varietal purity standards exist which allow differing levels of purity. Numerous studies show that preventing adventitious presence of GM traces in conventional seeds is next to impossible and expensive.

Adventitious presence of products that have undergone safety assessments are not a safety issue. A GM crop can be grown only after it has been extensively tested and approved as safe for humans and the environment under rigorous approval processes. The presence of traces of the same tested and approved GM material in a non-GM crop is obviously equally safe to the consumer and to the environment.

The example of maize

A report called “The Economics of Adventitious Presence Thresholds in the EU Seed Market”ⁱ explains in detail the basic features of seed production and the variable cost determinants for maize. The report explains that maize seed firms have long planning horizons because product development and commercialization are characterized by lengthy gestation lags.

Purity control is most challenging during the final stage of maize production because of the large amounts of commercial seeds produced in open environments. Seeds are grown in areas of maize grain production and maize seed firms invest significant effort to secure fields with desired isolation distances. The report explains that a key determinant of product quality is seed purity and that this is carefully protected at all stages of seed breeding, harvesting and handling through advanced quality control systems.

Adventitious presence is a problem that affects all seed companies. It is not particular only to companies who sell GM seeds because conventional seed companies produce their seeds in the same geographic areas around the world as GM seeds are grown.

Many techniques are applied to limit adventitious presence, including:

Isolation. Distance requirements as described by regulatory agencies and seed certification agencies. Additional internal requirements around isolation distance, border rows, separation of events/traits and similar genetic lines. Additional monitoring is conducted to affirm isolation distance etc.

Machinery/equipment cleanout. During planting, harvest and handling, physical mixtures are avoided by following best practices cleanout procedures and monitoring of planters, harvesters, seed storage and seed conditioning equipment.

Roguing and pollination. Best practice procedures are established and emphasized with field crews who remove off-type plants and conduct hand-pollinations in plant breeding nurseries. Care is taken to keep activities in non-transgenic and transgenic plant breeding nurseries separate from each other. Seed production fields also emphasize roguing and monitoring of pollination.

Labeling of material inventory. Care is taken to ensure electronic inventory records match physical inventory. Use of proper labeling, including use of barcodes, is conducted to ensure proper identification of materials. Care is taken to ensure materials are discarded in an appropriate and timely manner with good record keeping.

Lab testing. Trait testing is conducted to ensure the presence of the trait of interest. Trait testing is also conducted to ensure the lack of non-target traits in materials.

3. The problem and two trends that are making it acute.

A new dilemma with a new technology

Varieties developed using genetic modification (GM) grow and reproduce and are being harvested, stored, processed and marketed in the same way as their “conventional” counterparts. They too must be checked for adventitious presence of off-types and other impurities, to ensure that they meet designated requirements of varietal purity. But the new technology also presents a new challenge in conducting these controls – not in controlling the GM seeds, but in controlling conventional seeds for adventitious presence of GM seeds.

Adventitious presence of GM seeds can occur in non-GM seed. Notably, the widespread cultivation of GM crops approved in southern American countries increases the possibility of their adventitious presence in non-GM seed produced in these countries. GM seed which has been approved in other mature regulatory schemes, outside the EU, and in many cases is pending approval in the EU (where it is subject to far longer delays) will inevitably find its way into the EU because cultivation, production and transport of conventional varieties cannot occur in a hermetically sealed bubble despite adherence to best practices.

The presence of a small amount of such safe, approved GM material in a non-GM crop therefore also poses no adverse risk to the consumer or to the environment.

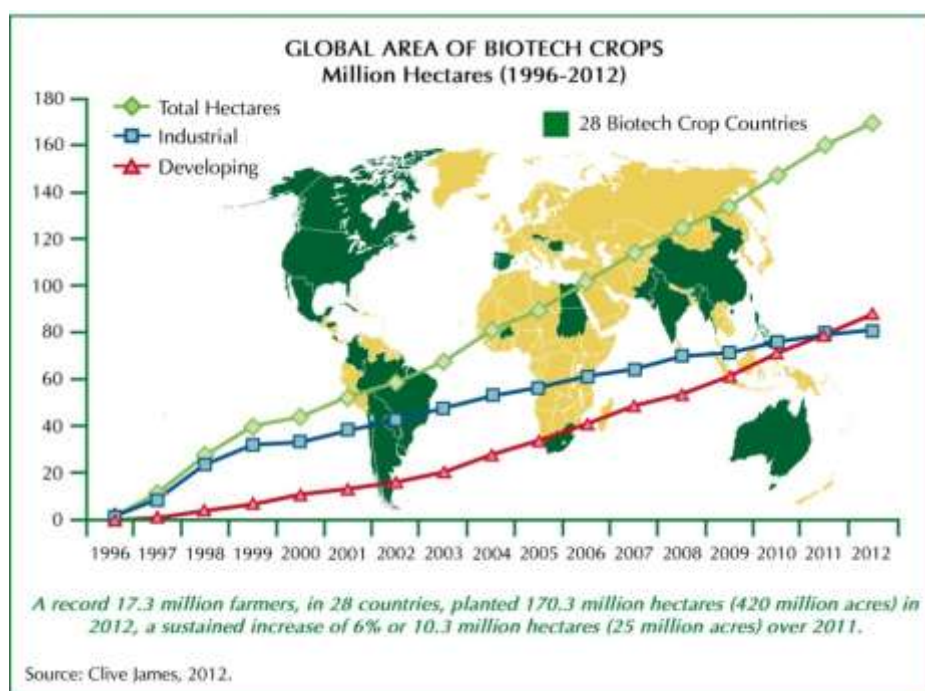
Two trends are coalescing that make the lack of an AP threshold more acute:

Trend 1: increasing presence of GM seeds globally,

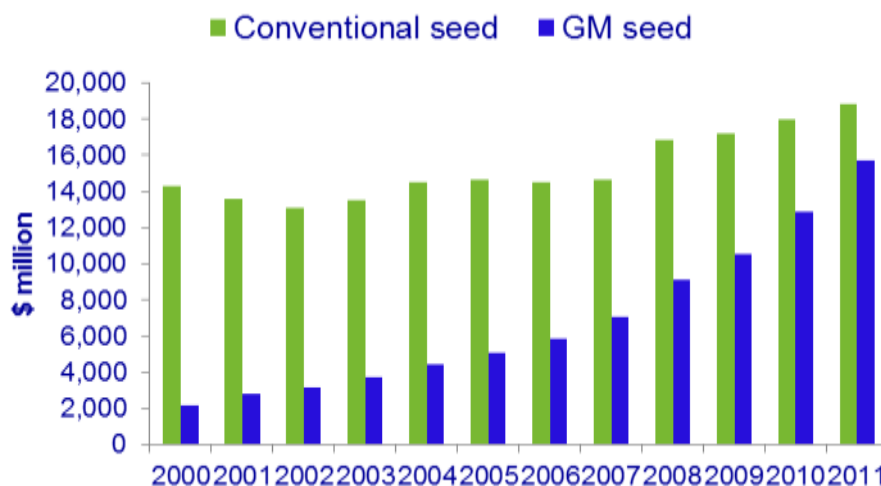
Trend 2: increasing trade of seeds globally.

Trend 1: Increasing presence of GM seeds (source: ISAAA, Clive James)

The number of GM seeds in circulation is increasing rapidly globally. In 1996, in the first year of cultivation, 1.7 million hectares were planted. In 2012 this has increased to 170 million hectares, in 28 countries. To supply this growing demand, more GM seed production is taking place.



The chart below shows that there is a rapid increase in the percentage of GM seeds as part of the overall commercial seed sector for major crops. (source: Philips McDougal insert reference)



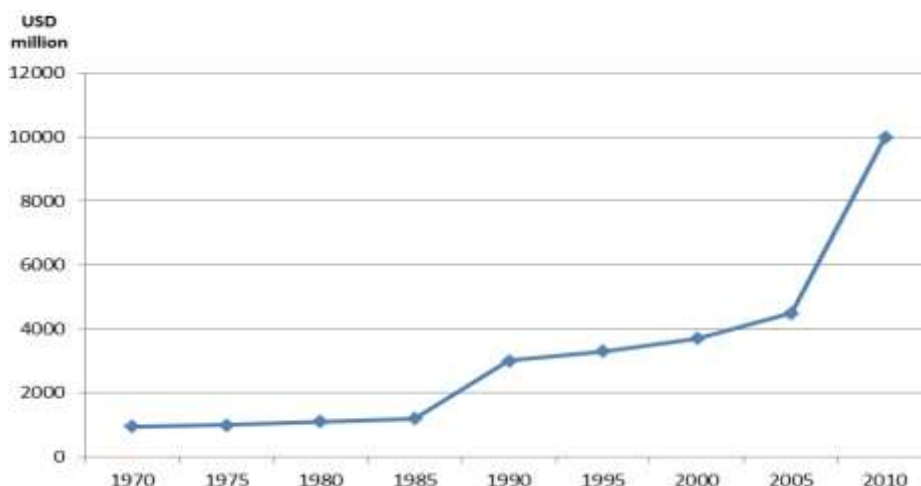
Trend 2: Increasing trade of seeds globally

The value of the global commercial seed market is estimated at 45 US\$ billion. The charts below show that there is a rapid growth of international trade of seeds. This trend should be seen in light of other trends, including: counter season production, faster speed of breeding, cheap and fast transportation and the development of hybrid varieties.

Size of the seed market (Source: derived from ISF data)

	2001	2007	2011
Global seed market	US\$ 30 billion	US\$ 35 billion	US\$ 45 billion
Internationally traded seed	US\$ 3.9 billion	US\$ 5.5 billion	US\$ 10 billion

Growth in international seed trade (source ISF)



Value of selected global and European markets in 2011 (in US\$ million) (source ISF)

Non-EU		In EU			
USA	12,000	France	3,600	United Kingdom	450
China	9,034	Germany	1,170	Czech Republic	305
Brazil	2,625	Italy	715	Hungary	300
India	2,000	Netherlands	585	Poland	260
Japan	1,550	Spain	450	Sweden	250

Euro/USD conversion rate of 1.3 has been used for these estimates

Current situation in the EU

Currently the EU applies a zero-tolerance approach. That means that if a single GM seed is found in a conventional seed batch, this batch cannot be used in EU territory. This applies to the one GM variety approved in the EU as well as the hundreds of GM seeds approved outside the EU in other countries, but not yet approved in the EU.

Recognizing that zero-tolerance is unworkable, the European Commission and the Member States approved in 2011, with a large qualified majority, a technical testing approach for GM presence in imported commodities. A 0.1% testing level for imported grains for use in animal feed was set with the intention to extend this to food in the near future.

Political background

Regarding the thresholds levels in seed, there has been strong political support from the public and private sector that 100% is not possible and that thresholds are needed.

Member States: European Ministers have twice unanimously requested an AP in seeds thresholds. In 2006, the Council of Agricultural Ministers invited the Commission to “...*come forward, as soon as possible, with Community labelling thresholds for seeds.*” In 2008, the Council of Environment Ministers unanimously invited Commission to “*adopt practicable AP in seeds thresholds as soon as possible*”.

European Commission: The European Commission has been aware of the need to address technically unavoidable presence for over a decade. In 2002, Commissioner Wallstrom wrote that setting tolerance thresholds is “*the only way to address the problem. Closing our market completely is not a viable option*”ⁱⁱ. In 2004, a debate in the College of Commissioners debate concluded that: “*labelling thresholds....should urgently be finalised*”. A second debate in 2005 in the College reconfirmed this. In 2007, the Commission’s mid-term review of Life Sciences asked for an threshold. In 2008, President Barroso’s Biotech Sherpa Group called for an AP threshold.

Scientific consensus: The Scientific Committee on Plants wrote in 2001 that seed thresholds were needed.ⁱⁱⁱ In 2006, a Commission-sponsored JRC study again emphasizes the urgent need for AP thresholds for seeds.^{iv} Many national scientific authorities have recommended the same.

European seed industry and farmers: The European seed industry, as well as European farmers’ organizations, has asked for an AP threshold levels for over a decade. Already in 1999 the seed industry requested the Commission to set threshold levels for adventitious presence of GMOs in conventional seed. Between 1999 and 2012, the seed industry and farmers have asked for an AP level in numerous letters, events and meetings with the Commission and Member States. In 2012, ESA and Copa-Cogeca together with 10 other food chain organizations asked Commissioner Dalli to adopt a “*technical solution for seed: a testing and sampling protocol for seed*”. The request was repeated to Commissioner Borg in late 2012.

Failed attempts

Over the last decade, the European Commission has made different separate attempts to set such thresholds. None of the attempts have made it beyond the College of Commissioners. In 2000, the Commission (DG Sanco) drafted a first AP threshold proposal. In 2002, the Commission stated the intention to produce a threshold^v. DG Sanco put forward a revised proposal. In 2003, an AP threshold proposal on the College of Commissioners agenda was retracted at the last moment. In 2004, DG Environment’s new proposal is retracted during inter-service consultation. In 2012, DG Sanco restarts work on a technical solution, but the change of Commissioner halts progress.

The combination of the trends set out before - growing adoption of biotech crops worldwide and the growing trade of seeds - has had **four indirect negative effects**:

1. **Costly incidents** in the EU where GM seed is being found in conventional seed batches.
2. Zero tolerance is leading to **increased operational costs** for seed companies, making it more challenging to operate in the EU compared to other regions.
3. Member States are reacting by **applying national tolerance levels** thereby eroding the Single Market.
4. European **agricultural competitiveness is negatively impacted** as the trade of conventional seeds has become more challenging.

Each of these negative effects is explained in detail below.

1. **Costly incidents**

There are a growing number of incidents which are becoming increasingly costly. The British Government's Central Science Laboratory estimated that there were over 300 incidents involving authorized and unauthorized GM seeds between 2001 and 2006. A look through the www.gmcontaminationregister.org also shows a high number of incidents. In Annex 1 of this report, seven case studies illustrate this point. Below are observations about five of them.

- A case in Germany in 2007 affected a medium sized German company. GM was found in oilseed rape at 0.03%. Damage to the company is estimated at €1.7 million with also high legal costs.
- Another case in Germany in 2009 affected a large German company. GM was found at less than 0.1% in maize seed. Because it was found early it only affected 5 hectares, but overall costs were still around €100,000.
- A case in Hungary in 2011 where it was claimed some 9,500 ha of maize fields were destroyed based on data from the Hungarian government stating they had found traces of unapproved GM varieties. Evidence was not produced, and additional testing discovered no traces. No verification or documentation of testing results was provided by authorities. The economic loss is estimated at between €23.5 million.
- In Germany in 2010, a larger company operating globally was affected. GM was found at less than 0.1% in maize seed. Cost was €4 million (down-payments for the farmers, destruction costs, costs for court cases, etc.) because 2,000 hectares had been planted already.
- In another case in Hungary from 2012 a batch of maize seed provided by a smaller conventional seed company was tested positive for GM at under 0.1%. The authorities ordered the destruction of about 1500 ha. It is estimated that the seed company in question would at least lose 1 years of Hungarian market turnover in compensation and possible criminal damages payments, estimated at about €3.75 million.

From these real incidents, a number of conclusions can be drawn:

- The challenge affects the entire seed sector, including companies that develop and sell GM seed and those that do not. Note that two of the companies mentioned in the case studies do not produce GM seeds. The reason it affects both GM seed and non-GM seeds companies is that conventional and GM seed production takes place in the same geographic areas.
- Large and small companies are negatively affected. Larger companies can deal with the problem in an easier way than smaller companies because their larger operations making it easier to operate more separated non-GM and GM machinery and transport lines. Because this entails higher costs, smaller companies find it economically more challenging.
- The examples above show that costs of incidents can be economically very impactful for affected seed companies and farmers. The examples show that the costs run into millions.
- There are increasing legal uncertainties. Different countries are applying different standards. Seed companies and their staff even face criminal proceedings in some countries for the adventitious presence of just tiny trace amounts. **Include something about Audits by ec**
- Farmers are negatively affected by these incidents. Perfectly safe harvests are destroyed because a 0.1% trace or less, of a GM product is found. In most other areas outside the EU, if these products are approved there, these grain products would enter the food chain and be consumed within months. Most other regions have functioning GM product approval systems.

2. Increasing operational costs

Zero tolerance is increasing the operational costs for seed companies, making it more challenging to operate in the EU compared to other regions. The section above shows that there are direct economic consequences through incidents for companies developing, selling and trading seeds.

The lack of a threshold level or at least of an agreed measuring methodology to define zero tolerance with more legal certainty ("technical solution") substantially and unnecessarily increases the cost of production of the final seed product –, with a negative impact on the competitiveness of seed production in the EU. There are four areas in the seed production process where costs increase as tolerance threshold levels for adventitious presence are lowered or lacking. These relate to operational changes necessary to comply with no, low or nationally differing AP thresholds levels.

- 1) In conventional seed growing areas, there are more requirements to increase the isolation distances of the seed crop from neighbouring maize fields. This is done through increasing border rows around the seed crop, increasing the number of male parent plants (pollinators) for hybrid seed production, and increasing the time between flowering of the seed crop and neighbouring maize fields by delaying planting;
- 2) Harvesting the seed crops separately which require more thorough cleaning of all machinery used in the stages of seed cleaning and processing, perhaps using dedicated machinery;
- 3) Testing each harvest of seed in the multiplication process to assess the presence, and level of adventitious presence of GM; and,
- 4) Discarding seed that has adventitious presence levels above those determined to be acceptable. The case studies above attest to this.
- 5) Legal and operational uncertainties due to differing threshold levels in different countries increases costs when moving seeds between different European markets. There have even

been cases where criminal proceedings have been initiated against seed companies and their staff because of detectable but extremely low levels of adventitious presence of approved GM in non-GM seed.

Modelling on empirical data provided by European hybrid maize seed producers to Prof. N. Kalaitzandonakes of the University of Missouri has shown that setting a labelling threshold for GM adventitious presence at 0.5% would increase costs on average by 44% and at a level of 0.3% on average by 54%. Because of smaller seed production fields in the EU compared to the USA, these costs are higher than for US seed producers (increases of 34% and 42% at labelling thresholds of 0.5% and 0.3% respectively).

The French Maize Seed Association, SEPROMA, estimated that seed discards would reach 25% and 30% if labelling thresholds were established at 0.5 and 0.3% respectively. This equates to 2.1 – 2.5 million bags of hybrid maize seed being discarded – at costs to the seed industry of between 50 and 60 million euros every year for these discards alone.

The European seed industry has provided to the Commission detailed data on the compliance costs of thresholds. These data were by and large confirmed by the Joint Research Centre. The Scientific Committee on Plants of 2001 found that even a threshold level of 0.1% (“detection level”) is impossible to achieve and to economically sustain under regular seed production conditions. It wrote that *“Achieving the 0.3% and the 0.5% thresholds will become increasingly difficult as GM crop production increases in Europe.”*^{vi} This is also recognized by various national and international bodies such as OECD and the AOSCA.

All studies and experiences show that no or excessively low threshold levels are practically and economically challenging. An excessively low threshold would drive costs up exponentially and could make seed production impossible for many growers and seed processors. While isolation procedures can reduce the occurrence of adventitious presence, available “isolated” farmland for seed production can be a practical limitation – particularly in Europe. Total separation of designated seed production areas from general farming areas is not feasible. In France, the largest producer of maize seed in the EU, the highest intensity of maize seed production is located in exactly those areas with a high intensity of commercial maize crop production^{vii}.

Small and medium-sized firms in the conventional seed sector are most impacted

The lack of adventitious presence thresholds or practicable EU-wide technical testing protocols is not just an issue for companies that are purely or predominantly biotech-based. It is a concern principally for small and medium-sized companies that are heavily involved in conventional plant breeding and seed production. Europe’s seed industry is particularly characterized by this SME dominated structure.

The lack of thresholds places these conventional seed companies at a significant competitive disadvantage. They cannot directly benefit from the technology, and at the same time they are victims of a regulatory approach that creates substantial legal uncertainty and financial burdens, even and especially those companies that choose not to develop and sell GM seeds. Smaller firms in Europe find this far more difficult to sustain than larger companies.

A 2001 survey of 62 large and small seed firms in the US concluded that compliance costs were unevenly distributed among seed firms of different size. Medium size firms face a competitive disadvantage against larger and smaller firms. Small firms might be less exposed to AP due to greater control of their land base and a limited number of hybrids and volume to manage. The study wrote that *“Larger firms might be less exposed to AP standards, because they can employ a broader set of cost-minimizing strategies. Larger seed firms can manage AP for a whole portfolio of parent lines and hybrids by shifting production across multiple national and international locations where they own processing facilities. Additionally, the high costs of quality assurance programs necessary to manage AP thresholds can be spread over larger volumes and numbers of hybrids. Structural impacts from AP regulatory standards could accelerate the disappearance of medium size seed firms in a renewed cycle of industry consolidation.”*^{viii}

3. Member States are setting national tolerance levels, thereby eroding the Single Market

Because no EU seed thresholds for GMOs have been set, Member States have imposed their own, often conditions on the seed industry.

Annex 2 shows the real and actual practices each Member State applies. The following conclusions can be drawn:

- **Each Member State government is applying different sampling and testing approaches and thresholds.**
- **There is no longer a fully functioning Single Market in seed trade across the EU.**
- **There is a high level of legal uncertainty regarding cases where the traces are not approved for cultivation in the EU, but “merely” for import and food/feed uses.**

The common market for seeds is eroding with restrictions to seed trade, limited availability of varieties to farmers and differing national standards. The major achievement of the EU's Seed Marketing Directives – the common market and free trade in seeds in Europe – is eroded. With different standards and methods being set by Member States, seed production and trade and, finally, choice for farmers is becoming increasingly difficult to ascertain. In the end, the Single Market is being denied to the seed industry and to farmers because of the failure to establish labelling thresholds.

Annex 3 shows a scenario is presented that shows a theoretical case study of the consequences of transporting a conventional seed lot across 10 different EU Member States, in which traces of an EU-approved GM seed is found. The scenario shows that:

- **Operators moving seed across EU countries have different market conditions in each market.**

ANNEX 2 AND 3 SHOW THAT THERE IS NO LONGER A FULLY FUNCTIONAL SINGLE MARKET IN SEED TRADE ACROSS THE EU.

4. Agricultural competitiveness negatively impacted as the trade to the EU diminishes

Seed firms produce conventional and GM seeds and cater to the EU markets, but seed trade flows from countries with commercial GM production (seeds and crops) to the EU where there are limited approvals of biotechnology traits have slowed substantially. These companies test all conventional seed lots and then select those that meet EU zero tolerance standard.

European agricultural competitiveness is negatively impacted as it becomes more challenging to source new GM and non-GM germplasm. The history of seed trade shows that the rise in yields seen across the past decades in most parts of the world is in large part due to the capacity to import and breed new and better varieties. Since the zero tolerance approach to GM, the ability to trade and import new varieties is severely challenged.

INSERT examples on this point

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1. The European Commission has been aware of the need to address technically unavoidable adventitious presence of non-EU approved GM seed for well over 12 years.
 2. It remains to be seen whether the 'New Regulation on Plant Reproductive Materials'^{ix} (replacing 12 Directives on seed and plant propagating material with one single act) will in fact address this issue. The Commission's 'Option and Analysis'^x consultation paper which forms the backdrop to the proposal referred merely to ensuring 'better consistency with the other EU policies' including on GMOs.^{xi}
 3. In absence of a harmonised tolerance threshold and enforcement protocols, the ability to market consignments containing *de minimis* levels of adventitious presence in the EU is effectively determined by the inconsistent enforcement practices and standards applied by each of the 27 EU Member States.
 4. Given the longstanding, public, documented acknowledgment by the Commission of the need for action to resolve this barrier to the functioning of the market, **it is appropriate to consider whether the Commission's inaction in these circumstances is in fact unlawful.** The Commission is granted a right of legislative initiative^{xii} which it is required to exercise in order to fulfil those Union objectives defined in the treaties. This includes three notable obligations (emphasis added):
 - '...establish an internal market. It shall work for the sustainable development of Europe based on balanced economic growth and price stability, a highly competitive social market economy, aiming at...a high level of protection and improvement of the quality of the environment. It shall promote scientific and technological advance',^{xiii}
 - '...define and implement a common agriculture... policy. The internal market shall extend to agriculture... and trade in agricultural products',^{xiv} and
 - '...common organisation [of agricultural markets] shall...exclude any discrimination between producers or consumers within the Union'.^{xv}

It is apparent that none of these objectives have come close to being adequately satisfied as regards the adventitious presence of non-EU approved GM seed. The Court of Justice has recognised that in the exercise of the powers conferred by the EU legislature, the Commission has broad discretion where its action involves political, economic and social choices and where it is called on to undertake complex assessments and evaluations^{xvi}.

However, there is no such complex assessment to be made in this case, on the basis that the Commission has recognised the need for legislative action on multiple occasions over many years (see next section). The only barrier to adoption of this necessary proposal for a legislative measure appears to be political resistance. Whilst such resistance might ultimately stymie the *adoption* of a legislative proposal there is no reason to believe that this provides a legitimate basis for the Commission to exercise its legislative discretion in a manner inconsistent with its Treaty obligations.

On the contrary, the failure to remedy this significant and longstanding anomaly for adventitious presence looks more like a manifest error of appraisal or a misuse of powers than a proper exercise of discretion. It is hard to see how persistent Commission inaction is consistent with its effective role as the guardian of the treaties.

The extreme dysfunction of the EU regulatory regime in this area has created an almost unique set of circumstances where there is a clear and documented longstanding position expressed by the Commission that action is required to address a serious regulatory problem in the internal market and yet no action has been taken.

5. These considerations are more compelling given that the Charter of Fundamental Rights establishes the ‘freedom to conduct a business’ (Article 16) and the ‘right to property’ (Article 17) as primary EU law obligations. Limitation on these is subject to the principle of proportionality and must be necessary and genuinely meet objectives of general interest recognised by the EU or the need to protect the rights and freedoms of others^{xvii}. This requirement is true even where the precautionary principle is relied upon.^{xviii} It is by no means clear (or clearly articulated by the EU legislator in the applicable EU measures) that a zero tolerance threshold for adventitious presence in this context is actually proportionate or necessary to achieve such objectives.
6. Even precautionary action cannot be taken on the basis of a purely hypothetical approach to risk.^{xix} **The fact that tolerance thresholds for low level presence in GM feed have been adopted (pursuant to Regulation No. 619/2011) is a striking indication of the absence of any such science-based rationale.^{xx} This discrepancy in approach rather suggests a breach of the principles of equal treatment or non-discrimination requiring that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified.^{xxi} The existence of a tolerance threshold in one context but not the other appears discriminatory.**
7. Such discrepancy may also, arguably, be challenged under the WTO’s Agreement on Sanitary and Phytosanitary Measures (‘SPS Agreement’).^{xxii} Despite the broad discretion that the SPS Agreement allows WTO Members in choosing the level of sanitary or phytosanitary protection that they deem appropriate in their territories, it also imposes a number of requirements on them with a view to avoiding instances of trade protectionism. Among others, the SPS Agreement requires that WTO Members demonstrate consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health.^{xxiii} In essence, WTO Members may not make arbitrary or unjustifiable distinctions in the levels of protection that they impose for comparable (albeit different) situations, if such distinctions result in discrimination or a disguised restriction on trade.
8. In those lines, it may be argued that **the distinction in the level of sanitary or phytosanitary protection that the EU deems appropriate regarding, on the one hand, GM seed (i.e. 0% threshold) and, on the other hand, GM feed (i.e. 0.1% threshold) is incompatible with its obligations under the SPS Agreement.** Not only the difference in the two thresholds appears *prima facie* arbitrary and not based on scientific principles, but it also results in *de facto* discrimination against third-country producers exporting their non-GM seed into the EU - as indicated by the fact that, due to the minimal production of GM seed in the EU, EU producers of non-GM seed have a clear advantage in being able to satisfy the 0% threshold *vis-à-vis* third-country producers of non-GM seed.
9. Additional arguments regarding the measure’s incompatibility with WTO law may be linked to a broader challenge against the EU’s pre-marketing approval scheme for GMOs. This could be on the basis of considerations relating to the EU scheme’s inadequate substantiation by scientific evidence, as well as to discriminatory treatment emanating from the “likeness” of GM and non-GM products.^{xxiv} It is needless to say that potential findings of such incompatibilities by a WTO Dispute Panel would have far-reaching consequences for the legality of the entire EU GMO regulatory scheme currently in place.

10. **Absence of a labelling threshold.** A further issue concerns the absence of any labelling threshold (an effective 0% tolerance) for the technically unavoidable adventitious presence of EU-approved GM seed in the non-GM seed under Directive 2001/18/EC. **This is striking because unlike for the adventitious presence of non-EU approved GM seed (discussed above) the EU legislator expressly envisaged that such a labelling threshold might be necessary.** The labelling requirement for any adventitious presence creates a significant documented additional cost throughout the supply chain. Given that the necessity of a labelling threshold is no longer seriously in doubt, the Commission is arguably failing to exercise its legislative discretion in a manner consistent with its obligations (as explained above as regards the zero tolerance for adventitious presence of non-EU approved GM seed). The failure to remedy this significant and longstanding anomaly for adventitious presence looks more like a manifest error of appraisal or a misuse of powers than a proper exercise of discretion. It is hard to see how this persistent Commission inaction is consistent with its effective role as the guardian of the treaties. Indeed, the fact that a contrasting legislative approach is evident in Directive 2001/18/EC which grants EU-approved GMO products for direct *processing* a 0.9% labelling threshold rather suggests a breach of the principles of equal treatment or non-discrimination.
11. As with the zero tolerance for the adventitious presence of non-EU approved GM seed, the compatibility with WTO law of the absence of any labelling threshold may be, arguably, examined under the provisions of the SPS Agreement.^{xxv} **Once more, the inconsistency with which the EU applies the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health may be challenged – this time regarding, on the one hand, GM seed (0% threshold) and, on the other hand, GMO products for direct *processing* (0.9% threshold).** In addition, another key argument may focus on the necessity of the measure, by supporting that a significantly less trade-restrictive measure (i.e. the setting of a higher threshold) is reasonably available to the EU and capable of achieving the level of protection which is deemed appropriate by it. In that regard, the EU will likely have little room to argue that the level of protection deemed appropriate may only be attained through a zero-threshold labelling scheme, as the EU legislator has expressly envisaged that setting a higher labelling threshold may be necessary. Finally, as noted above, the measure's incompatibility with WTO law may also be linked to a broader challenge against the EU's pre-marketing approval scheme for GMOs.

Political solutions

What is needed in the EU is: recognition of the two trends and their negative effects, and action to address these negative effects.

The actions are for the European Commission and the Member states to take the political responsibility to restore the Single Market in seeds across the EU. This can be done in two steps:

- Step 1 is to put forward and agree as a matter of urgency a common measuring methodology. An appropriate methodology is set out in Annex 4.
- Step 2 is to set clear and practicable thresholds for labelling of seeds, in situations where there is an accidental presence in conventional seed of small traces of GM seed.

These two steps would eliminate diverging national approaches to seeds labelling, and by replacing uncertainty with consistency, would provide clarity and confidence to industry, farmers and consumers. EU agreement on such rules would mean that plant breeders and seed producers would know precisely when they have to label conventional seed for adventitious presence – and when they do not.

The above two actions must be led by the European Commission with the greatest urgency. There is a decade of political recognition from the Commission that action is needed. There is a wealth of scientific and other data showing the impact of the issue. There is ample political support from many Member States to move ahead. In this report, clear evidence is presented of the failure of the Single Market, and of the responsibility of the Commission under the Treaties to address this.

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Case 1: Germany 2007

Context

After having testing oilseed rape batches with negative results in their internal monitoring system, a medium-sized company (Deutsche Saatveredelung, DSV) sold the seed lots. Late in the sales season, when in several parts of Germany sowing had already started, the German officials of Northrhine-Westfalia tested one of the batches as positive for minor GMO-traces. At the moment when NRW informed the other Federal States, nearly 1.500 ha were already sown all over Germany. Federal States instructed the destruction of fields sown with seed of the respective seed lot. Despite several negative testing results from different laboratories, the officials only considered their single positive result without any verification (B-sample).

Crop	Oilseed Rape
Presence level	0.03 %
GM event found	Probably Falcon GS40/90
Regulatory status of GM event	no approval for cultivation
Economic consequences	The Company estimated their financial loss of about 1.7 Mio €. In addition there are high costs for running court cases.
Regulatory background in country	Germany operates a very strict interpretation of zero tolerance and rejects the verification of assumed positive results.
Seed provider	Deutsche Saatveredelung is a medium sized company with an annual turnover of about 96 Mio. € and 340 staff. DSV is based in Lippstadt (NRW) and has global activities in nearly every continent. The main crops are oilseed rape, grass and cereals. http://www.dsv-saaten.de
Additional reading	http://www.gmo-compass.org/eng/news/messages/200709.docu.html#154

Case 2: Germany 2009

Context

Within the annual seed monitoring Baden-Württemberg had found minor GMO traces in 5 batches of maize seed. Because of the early information to the breeders nearly all of the concerning seed could be blocked from the market. Only 5 ha had been planted with that seed in the end. The officials ordered the immediate destruction of these 5 ha.

Also the officials of Saxony found GMO-traces in other seed lots. Because they informed the other Federal States much too late (after sowing), one positively tested variety had already been sown in Baden-Württemberg (on ca. 170 ha) and in Rhineland-Palatinate (on ca. 70 ha).

BW and RP recommended the farmers to destroy the plants after germination; but they also accepted the alternative of growing and utilization for energy production under certain conditions (isolation distances, testing of the harvest products, post harvesting monitoring).

Crop	Maize
Presence level	< 0.1%
GM event found	NK603
Regulatory status of GM event	Not approved for cultivation. Approved for Food/Feed use
Economic consequences	ca. 100.000€
Regulatory background in country	Germany operates a very strict interpretation of zero tolerance and rejects the verification of assumed positive results.
Seed provider	KWS (http://www.kws.de)
Additional reading	http://murschel.de/userspace/BW/bernd_murschel/Dokumente/Antraege_Anfragen/2009/Antrag036_MON_NK_603.pdf

Case3: Germany 2010	
Context Officials of Lower Saxony had found minor GMO-traces in seed lots of Pioneer. Because the information was repressed for a long time the concerned seed had been sown of 300 farmers in seven Federal States on nearly 2.000 ha. All Federal States ordered the destruction of those fields.	
Crop	Maize
Presence level	< 0.1%
GM event found	NK603
Regulatory status of GM event	Not approved for cultivation. approved for feed/food use
Economic consequences	ca. 4 Mio. € (down-payments for the farmers, destruction costs, costs for court cases, ...)
Regulatory background in country	Germany operates a very strict interpretation of zero tolerance and rejects the verification of assumed positive results.
Seed provider	Pioneer HiBred http://public.pioneer.com/portal/site/Public/?locale=de_DE
Additional reading	http://dip21.bundestag.de/dip21/btd/17/025/1702511.pdf http://dip21.bundestag.de/dip21/btd/17/035/1703558.pdf
Case4: Hungary 2011	
Context In Hungary, in June 2011 the Government announced the destruction of 400 ha of maize fields because they claimed the seed farmers bought from Monsanto was contaminated with genetically modified maize. Monsanto contested the action saying their independent test showed there was no contamination. No verification or documentation of testing results was provided by authorities and the results of the seed company were not accepted. By August 2011, the Rural Development Ministry State Secretary Gyorgy Czervan said that 8,500-9,000 hectares were being destroyed because of maize seed containing genetically modified (GM) seeds. This total included 4,500 ha of suspected GM contaminated maize and approx. 4,000 ha of "buffer zone". It was reported that the 225 producers affected would be compensated with a total of HUF 360,000. In the end it seems that at minimum 5.000 ha were actually destroyed. n.b: Some of the seed bags allegedly containing AP had initially been distributed in Romania, with the approval of local authority. A Hungarian retailer later brought the seed to Hungary where it suddenly didn't meet the Hungarian national requirements.	
Crop	Maize
Presence level	Below 0.1 %
GM event found	MON 810; ??? ; not substantiated by authorities
Regulatory status of GM event	Approved for cultivation in the EU
Economic consequences	loss of parts of the year's Hungarian turnover; compensation of farmers by lump sum of several million EUR to avoid additional possible criminal charges and payment of further damages (up to 2 billion HUF per incident depending on magnitude). Economic loss: approx. 2.500 EUR/ha x 9.500 ha = > 23,5 mio. EUR (i.e. for 5.000 ha = 12.5 mio EUR)
Regulatory background in country	Hungary operates a very strict interpretation of zero tolerance. Specific GM related obligations were introduced in Hungarian seed law for seed imports; on these, ESA filed a complaint with the Commission in summer 2011 (v. ESA_12.0603) which lead to partial revision of the respective paragraphs. Still, the Hungarian law requests e.g. handing over and destruction of seed in case GM traces are detected. In addition, sentences of up to 2 years imprisonment and up to 2 billion HUF damages are set for GM introductions in Hungary.
Seed provider	Monsanto is the world no. 1 seed company. www.monsanto.com
Additional reading	http://www.gmcontaminationregister.org/index.php?content=re_detail&gw_id=371&reg=reg.1&inc=0&con=3&cof=0&year=0&handle2_page=1 http://www.bbj.hu/economy/hungary-destroys-crops-on-8500-9000-hectares-because-of-gm-tainted-maize_59473

Case 5: Hungary 2011	
Context	
During 2nd week of August 2011, a farmer (László Meleg) in Hajdú-Bihar county (Eastern Hungary) was called and informed over the phone by MGSZH that his 6 ha (24 bags) of Pioneer's M22 soybean proved to be positive and he must be prepared to destroy it. It turned out that after the first allegedly positive GMO test results in April, the Minister of Rural Development ordered the collection of 100 seed samples at farm level as well. MGSZH collected the samples in the first half of May. It happened that on May 6, they sampled again the batch (USA-IA-10-69-0785) that had already been tested in April (the negative certificate from MGSZH was received on April 22).	
Thus, from the same batch, there is a negative and a positive result issued by the same MGSZH lab. The company was not informed about this new positive result, only the farmer, and only verbally. The farmer received the destruction order from MGSZH on August 25 2011. The deadline for chopping the 6 ha of M22 Pioneer soybeans was August 31. The farmer destroyed the 6 ha soybeans until the deadline. The total damage suffered by the farmer was fully compensated by Pioneer.	
Crop	Soybean
Presence level	< 0.1%
GM event found	M 22
Regulatory status of GM event	Not approved for cultivation approved for feed/food use
Economic consequences	6 ha destroyed; loss of 15.000 to 18.000 EUR
Regulatory background in country	Hungary operates a very strict interpretation of zero tolerance. Specific GM related obligations were introduced in Hungarian seed law for seed imports; on these, ESA filed a complaint with the Commission in summer 2011 (v. ESA_12.0603) which lead to partial revision of the respective paragraphs. Still, the Hungarian law requests e.g. handing over and destruction of seed in case GM traces are detected. In addition, sentences of up to 2 years imprisonment and up to 2 billion HUF damages are set for GM introductions in Hungary.
Seed provider	Pioneer HiBred http://public.pioneer.com/portal/site/Public/?locale=de_DE
Additional reading	

Case 6: Hungary 2012	
Context	
In Hungary, in June 2012, a batch of maize seed provided by a smaller German (conventional) seed company was tested positive for adventitious presence of GMOs (under 0.1%) at farm level. The authorities have ordered the destruction of the crops (about 1500 ha).	
Crop	Maize
Presence level	Below 0.1 %
GM event found	MON 810 (?) ; not substantiated by authorities
Regulatory status of GM event	Approved for cultivation in the EU
Economic consequences	It is estimated that the seed company in question would at least lose this year's Hungarian turnover in compensation and possible criminal damages payments. Economic loss 2.500 EUR/ha x 1500 ha = 3.75 mio. EUR
Regulatory background in country	Hungary operates a very strict interpretation of zero tolerance. Specific GM related obligations were introduced in Hungarian seed law for seed imports; on these, ESA filed a complaint with the Commission in summer 2011 (v. ESA_12.0603) which lead to partial revision of the respective paragraphs. Still, the Hungarian law requests e.g. handing over and destruction of seed in case GM traces are detected. In addition, sentences of up to 2 years imprisonment and up to 2 billion HUF damages are set in criminal law for GM introductions in Hungary.
Seed provider	Saaten-Union is an umbrella distribution structure for 7 small breeders with a turnover of about 146 m €. Saatenunion is based near Hannover and has activities and daughter companies in about 10 European countries including the UK and France, as well as many new EU MS, Ukraine and Russia). Apart from maize, their main products are wheat, barley and rhye.
Additional reading	http://www.xpatloop.com/news/70846

Case 7: Germany 2012	
Context During the routinely seed testing the officials of Baden-Württemberg found GMO-traces in several batches of one <u>organic propagated</u> soybean variety. The seed had to be blocked and can't be used for sowing.	
Crop	Soybean
Presence level	< 0.1
GM event found	MON40-3-2
Regulatory status of GM event	Not approved for cultivation; approved for feed/food use
Economic consequences	According to information of the concerned company 28 t of the seed (correlate to nearly 38% of the propagation material for the German company's market) can't be used for sowing. Thereby the company has a problem to ensure the resources of their production chain.
Regulatory background in country	Germany operates a very strict interpretation of zero tolerance and rejects the verification of assumed positive results.
Seed provider	Taifun (a producer of biological tofu products who organised the whole product chain – from seed propagation up to marketing – to assure that only non-GM products are processed and sold) http://www.taifun-tofu.de/en/sojaanbau/taifun_tofu_leitlinien.php?NID1=2&NID2=1&NID3=0
Additional reading	http://www.taifun-tofu.de/de/img_pool/Information_Saatgutsituation.pdf https://www.landwirtschaft-bw.info/servlet/PB/show/1368850_11/tz_GVO-Saatgut-Monitoring%20Soja%202012%20Endergebnis%20.pdf

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Country	Crop	Covered events (status of approval)	Threshold level	Legal basis/Official measures in place? <i>Yes with text reference No or not known</i>	Official testing in place?	Comments
Austria	Maize	Any event	0.0% / 0.1%	YES Saatgut-Gentechnik-Verordnung 2001 StF: BGBl. II Nr. 478/2001, in the applicable version Methoden für Saatgut und Sorten; Amtliche Nachrichten 20/20074	Yes	3.000 seeds have to be tested for each seed lot certified or marketed in Austria by responsible company. There is 0-tolerance in this first analysis. Authority takes spot samples and analyses: Threshold is 0,1% if valid certificate exists or 0,0% if no valid certificate exists for seed lot.
	Oil and Fibre crops (Brassica rapa & napus, soybean)	Any event	0.0% / 0.1%		yes	
	Potatoe	Any event	0.0% / 0.1%		Yes	
	Vegetables (Tomato for industrial use, Chicory)	Any event	0.0% / 0.1%		Yes	
	Forages		0.0 %	Not covered by the legislation	No	
Belgium	Maize	Cultivation approved events	0.1 % (0.3 % in Wallony)		Yes	Test at random ; limited testing for trade inside EU
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
Bulgaria	Maize	Cultivation approved events	0,5 %	Genetically Modified Organisms Act <i>Promulgated, State Gazette No. 27/29.03.2005 (effective 1.06.2005)</i>	No	Ban on MON 810 in January 2011
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
Cyprus	Maize					
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
Czech Republic	Maize;	Product intended for direct processing	0.9%	Regulation (EC) No 1830/2003	Yes	

	Soybean; Potato			Act (CZ) No 78/2004		
Denmark	Maize	Threshold at detection or quantification? 0,1%			No	
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
Estonia	Maize		0.1	Deliberate Release Into the Environment of Genetically Modified Organisms Act ¹ Passed 14 April 2004 (RT2 I 2004, 30, 209), entered into force 1 May 2004. Draft: regulation of MoA on application form and requirements, processing of application and additional documents for processor of GM agricultural plants. Draft: regulation of MoA on training program of GM processors, requirements for certification, order for certification and frequency of follow up trainings. Draf : regulation of MoA on Precise requirements of notification and processing of GM agricultural plants	Yes	At random
	Oil and Fibre crops		0.1		Yes	At random
	Potatoe		0.1			
	Vegetables		0.1		Yes	Tomato, at random
	Forages		0.1		Yes	Soya, at random
Finland	Maize					
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
France	Maize	Any events	No detection	No	Yes	In the law , (LOI no 2008-595 du 25 juin 2008 relative aux organismes génétiquement modifiés) provision of a labelling threshold to be defined by decree. Decree notification was
	Oil and Fibre crops	Any events	No detection		yes	
	Potatoe	Any events	No detection			
	Vegetables	Any events	No detection			

	Forages	Any events	No detection			issued by FRA in 2012.
Germany	Maize	Cultivation approved events	0.1 / 0,0%	Yes LAG Methodenkonzept zur Überwachung von Saatgut auf GVO-Anteile (2006) LAG Vollzugsempfehlung für ein einheitliches Vorgehen der Überwachungsbehörden	Yes	Deadline for official testing and result transferring: CW 13. Threshold is not valid for MON810 because of the national ban, thus level in practice at 0.0%
	Oil and Fibre crops		0.00 %		Yes	Deadline for official testing and result transferring: CW 31.
	Potatoe			Concept is still in development	Yes	Single test done in parallel to the testing of bacterial diseases
	Vegetables					
	Forages					
Greece	Maize	Cultivation approved events	< 0,5 %	Yes Resolution : 33.2.657/ 7 fev 2001 Covers Events authorized for cultivation	Yes	Covers events authorized for cultivation Analysis data provided by company needs to be certified by an OECD agency - tests by official increase - GR: for a positive result of analysis between 0.1 and 0.5%, it is mandatory to quantify the authorized events present (Mon810-T25) and produce a GNIS/ENSE or other official certification authority certificate
	Oil and Fibre crops	Cultivation approved events				No presence allowed. In case of a positive local official testing result, there is a right to request a second analysis. In case both analysis are positive, seed to be sent back to supplier or to be destroyed.
	Potatoe	Cultivation approved events				
	Vegetables (Tomato)	Cultivation approved events				
	Forages	Cultivation approved events				
Hungary	Maize	Any events	„no contamination“	YES Basic Decree March, 48/2011 2003 2004 and amended by 16/2011 in March July, 69/2011 in July	Yes	The decree covers maize, rice, soybean, rape, flax
	Oil and Fibre crops	Any events	no contamination			The decree states : "In the case of all seed batches originating from EU Member States, or from a third country deemed equal in respect of seed qualification the first distributor in Hungary shall without delay, but by no later than within 5 days, notify the

						<p>authority in writing of the importation and the volume of the seed batch.</p> <p>The authority examines the GMO free status of the seed batches on the basis of a risk assessment. The authority shall make available to the notifying distributor the result of the test within 30 days from the drawing of the sample</p> <p>In the case of seed batches produced in Hungary, the authority on the basis of a risk assessment, take samples from the relevant seed batch at the time of the sealing for the purpose of the GMO testing. The provisions specified earlier shall be applied to this case also.</p>
	Potatoe					
	Vegetables		No contamination	Basic Decree 50/2004 amended by 14/2004 2011 in February and 1/2012 in January		The decree covers tomato, sweet corn, egg-plant, cucurbitaceous species, All seed lots are intended for the Hungarian market have to be tested by the authority
	Forages					
Ireland	Maize				Yes	Certificate (issued by recognised laboratory acceptable to the relevant certifying authorities) requested for commercial seed and hybrid registration at detection level , Sampled seed lots are blocked until release of analysis result ,
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
Italy	Maize	Any event	Absence of GMO = de facto < 0.05 %	YES Decree: Nov 27 2003 (Gazzetta Ufficiale N. 281 del 3 Dicembre 2003)	Yes	At least 20% of lots tested every year, at random (de facto, close to 100%), by Seed certification agency (ENSE), Anti-fraude Service and Custom agency ; All probes used even if not JRC validated; System of fines in case of positive result
	Oil and Fibre crops (soybean)	Any event	Absence of GMO = de facto < 0.05 %	YES Decree: Nov 27 2003 (Gazzetta Ufficiale N. 281 del 3 Dicembre 2003)	Yes	At least 20% of lots tested every year, at random (de facto, close to 100%), by Seed certification agency (ENSE), Anti-fraude Service and Custom agency ;

						All probes used even if not JRC validated; In case of positive result, seeds are seized, seed company is fined and the legal representative is reported for criminal (penal) violation.
	Potatoe				No	
	Vegetables				no	
	Forages				no	
Latvia	Maize					
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
Lithuania	Maize	Cultivation approved events	0.9 %			
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
Luxembourg	Maize					Certificate (result of analysis) requested for corn hybrid registration and strongly recommended for commercial seed
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
Malta	Maize					
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
Netherlands	Maize	Cultivation approved events	< 0.5 % (0.3%)	No	No	Currently there are no official requests for AP tests in seed. Yearly the monitoring of round 30 samples takes place. In principal the gentleman's agreement is followed for approved events <0.5% and for non-approved it is not clear. The percentages found in the samples are almost always zero.
	Oil and Fibre crops			No	No	
	Potatoe			No	No	
	Vegetables			No	No	
	Forages			no	No	
Poland	Maize	Any event approved for food	0.5 %	No; gentlemen's agreement	Yes	The GMO's seeds are not allowed to be commercialized in Poland

	Oil and Fibre crops	and feed use in EU				
	Potatoe					
	Vegetables					
	Forages					
Portugal	Maize	Cultivation approved events	< 0.5 %		Yes	
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
Romania	Maize	Cultivation approved events	0.5 % for autogamous 0.3 % for allogamous	Yes Minister of Agriculture Order no. 232 , October 20, 2010	Yes	CONDITION for CERTIFICATION: if seed of non-GM varieties may contain authorized GMOs, it must be officially tested for certification. No specified rules under what circumstances/technical rules GM testing is to be carried out
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
Slovenia	Maize	Any event?	< 0.1 %			Follows Austria - Certificat requested for hybrid registration Test done at random or mandatory lot testing?
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
Spain	Maize	Sum of each single event *	< 0.5 %	Yes Mail exchanges with OEVV (National Seed Authority)	Yes	* single event either authorized for Cultivation or Food & Feed or having a positive opinion from EFSA. For events having only a positive EFSA opinion and not yet authorized, the sum of these events may not exceed 0.1% (within the 0.5%); Tests done on all certified seed lots (maize for all use) without certificate issued by an accredited laboratory

	Oil and Fibre crops	Sum of each single event *	< 0.5 %	Yes Mail exchanges with OEVV (National Seed Authority)	Yes	* single event either authorized for Cultivation or Food & Feed or having a positive opinion from EFSA. For events having only a positive EFSA opinion and not yet authorized, the sum of these events may not exceed 0.1% (within the 0.5%); Tests done on all certified seed lots (maize for all use) without certificate issued by an accredited laboratory
	Potatoe				No	
	Vegetables				No	
	Forages				No	
Sweden	Maize	Any event	< 0.01 % (e.g. 'zero tolerance' with regards to AP in seed)	No – no specific legal text relating to adventitious presence in seed or specification of threshold levels	No	Resent event (2010) with AP of non-approved GM-event in a seed multiplication field of Amflora (GM potato). Fraction of a % AP led to the decision, by the Swedish CA, of total harvest destruction of seed potatoes produced
	Oil and Fibre crops					
	Potatoe					
	Vegetables					
	Forages					
United Kingdom	Maize	Cultivation approved events	theoretically < 0.5 % (seed must be labelled if GMAP >0,5%), in practice 0.1% with labelling at >0.1% No detection at 0.1 %	UK adopted EC 0.5% interim threshold for approved events in 2001 but no company has ever tested this and in practice 0.1% is the applicable threshold.	Not routinely	Current practice is to apply the level of detection with labelling above 0.1% though in practice such seed is not marketed. Voluntary GM seed audit is offered by officials for Brassica rapa, Brassica napus, Zea mays and Glycine max. Audit is based on due diligence and/or test certificate. Participation in audit does not absolve participants of legal obligations. Letter of assurance required for acceptance of seed into official trials.
		Other events				
	Oil and Fibre crops	All events	0.1%		Not routinely	
	Potatoe					
	Vegetables					
	Forages					

In this section a theoretical case study of GM presence in seed and differing Member State approaches to this seed lot is presented. Seed lot “X” is tested by company ‘Y’ for presence of GM. This case study assumes that GM traces are found in batches of conventional seeds, in amounts of either below 0.1% (1st and 3rd columns from the left) or above 0.1% (2nd and 4th columns from the left).

The left half of the table below focuses on what happens in different Member States if such traces come from the maize event MON810, which is approved for cultivation in the EU. The right half of the table below focuses on what happens if such traces come from other EU-approved events (presently almost in all cases for food feed/ import uses but not for cultivation). Seed bags from this lot go to:

- Netherlands
- Germany
- Poland
- Hungary
- Austria
- France
- Spain
- Romania
- UK
- Italy

In case all countries apply their regular sampling and testing scrutiny and detect a presence, these are potential consequences.

	MON 810		Other EU approved events	
Country	< 0.1	> 0.1	< 0.1	> 0.1
NL	Sowing and use	Sowing and use up to a level of max. 0.5	Sowing and use	Unclear
DE	Recall (if possible); or field destruction or use for energy etc.	Recall (if possible); or field destruction	Recall (if possible); or field destruction	Recall (if possible); or field destruction
PL	Sowing and use	Sowing and use up to a level of 0.5%	Sowing and use	Sowing and use up to a level of 0.5%
HU	Seed lot destruction; Field destruction; Compensation of farmers; Criminal charges	Seed lot destruction; Field destruction; Compensation of farmers; Criminal charges	Seed lot destruction; Field destruction; Compensation of farmers; Criminal charges	Seed lot destruction; Field destruction; Compensation of farmers; Criminal charges
AT	Sowing and use in case first test result was negative (=0)	unclear; no marketing and possible field destruction	Sowing and use in case first test result was negative (= 0)	Unclear; No marketing and possible field destruction
FR	Recall, associated with full traceability. Field destruction could occurred	Recall, associated with full traceability. Field destruction could occurred	Recall, associated with full traceability. Field destruction could occurred	Recall, associated with full traceability. Field destruction could occurred
ES	Sowing and use	Sowing and use	Sowing and use	Sowing and use
RO	Sowing and use	Sowing and use	Unclear	Unclear
UK	Sowing and use	Unclear; case by case decision	Sowing and use	Unclear; case by case decision
IT	Sowing and use If below 0.049 declared as '0'; If above 0.049 rejected for sowing, seed seized, company fined and criminal charges	rejected for sowing, seed seized, company fined and criminal charges	Sowing and use If below 0.049 declared as '0'; If above 0.049 rejected for sowing, seed seized, company fined and criminal charges	rejected for sowing, seed seized, company fined and criminal charges



ⁱ INSERT

ⁱⁱ See Commissioner Wallström's reply to questions submitted by MEP Graefe zu Baringdorf during the sitting of 24 October 2002 as part of the European Parliament's debate on 'Adventitious presence of GMOs in seeds.

ⁱⁱⁱ http://ec.europa.eu/food/fs/sc/scp/out93_gmo_en.pdf

^{iv} Insert

^v DG SANCO/1542/02

^{vi} Scientific Committee on Plants - Opinion concerning the adventitious presence of GM seeds in conventional seeds. (7 March 2001) http://europa.eu.int/comm/food/fs/sc/scp/out93_gmo_en.pdf

^{vii} See. Inter alia Scientific Committee Opinion of 2001; results of farm scale trials in the UK; German large scale trials of 2004 and 2005; JRC study of 2006; Reckenholtz study of 2005/2006 and N. Kalaitzandonakes economic studies of 2004 and 2005.

^{viii} Insert Dr Nick study reference "(Kalaitzandonakes, 2001

^{ix} Which is listed in the Commission's Work Programme for 2013 (under Annex II, Simplification and Regulatory Burden Reduction initiatives).

^x 'OPTIONS AND ANALYSIS OF POSSIBLE SCENARIOS FOR THE REVIEW OF THE EU LEGISLATION ON THE MARKETING OF SEED AND PLANT PROPAGATING MATERIAL' (May 2011).

^{xi} This is not encouraging, given that the clear indication in the earlier October 2008 FCEC report for DG SANCO on 'Evaluation of the Community *acquis* on the marketing of seed and plant propagating material (S&PM)' that a thresholds could be simply achieved in the short term (p.8). Responses from its qualitative surveys indicated 'that 65% of respondents consider that the Community legislation on authorisation of GMO's has had a negative impact on the free marketing of S&PM, mainly because of the lack of thresholds for the adventitious presence of GMOs in non-GM seed lots. When considering the group 'Suppliers active in the seed sector', this proportion increases to 91%' (paragraphs 49-50).

^{xii} See Article 17 of the Treaty on European Union (TEU).

^{xiii} Article 3 of the TEU

^{xiv} Article 38 of the Treaty on the Functioning of the European Union (TFEU)

^{xv} Article 40(2), TFEU

^{xvi} See Case C-344/04 *IATA and ELFAA* [2006] ECR I-403, paragraph 80

^{xvii} Case C-61/11 *Denise McDonagh v Ryanair Ltd.*, paragraph 61

^{xviii} Case T-13/99 *Pfizer*, para. 411; Case T-70/99, *Alpharma*, paragraph 324.

^{xix} Case T-13/99 *Pfizer Animal Health SA v. Council* and Case T-70/99 *Alpharma Inc. v. Council*.

^{xx} Moreover, the various incidents non-EU approved GM low level presence of food or feed have been responded to with European Food Safety Authority independent scientific opinions concluding that whilst the available information was not sufficient to complete a comprehensive risk assessment, on the basis of the information available, it could conclude that the imports did not pose an imminent safety concern to humans or animals. There is no indication that a similar review of available information could not be undertaken (in advance) in order to facilitate the lawful market access of adventitious levels of non-EU approved GM seeds in non-GM consignments. The choice not to adopt such a scheme appears to be political rather than science-based and is accordingly disproportionate.

^{xxi} Case C-344/04 *IATA and ELFAA*, paragraph 95

^{xxii} This is in line with the findings of the WTO Panel in *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291,292,293/R, 29 September 2006, where the term "SPS measure" was interpreted in a rather broad way and, therefore, Directive 2001/18/EC was found to be subject to the more stringent requirements of the SPS

Agreement (compared to those applicable, in particular, under the WTO's Agreement on Technical Barriers to Trade). See paragraph 7.436 of the Report.

^{xxiii} See Article 5.5 of the WTO Agreement of Sanitary and Phytosanitary Measures.

^{xxiv} See Article III.4 of the General Agreement on Tariffs and Trade. In *European Communities – Measures Affecting the Approval and Marketing of Biotech Products (supra)*, Argentina did project a claim in these lines but the Panel rejected it as not having been properly established by the complainant.

^{xxv} In *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, it was found that the labelling requirement imposed in Directive 2001/18/EC is intended to protect human health and the environment from risks arising from the deliberate release of GMOs into the environment and is, therefore, subject to the disciplines of the SPS Agreement (see paragraph 7.390). However, the Panel Report did not include a finding on whether the labelling requirement imposed is actually consistent with the SPS Agreement (see paragraph 7.392).