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The European Association for Bioindustries

ADVENTITIOUS PRESENCE BRINGING CLARITY TO CONFUSION

ADVENTITIOUS PRESENCE – BRINGING CLARITY TO CONFUSION

Seed producers, plant breeders and farmers want the European Union to bring in new rules to respond to the still-unresolved challenge of low level presence of GMOs in seed which threatens these industries' ability to compete successfully on world markets.

These new rules would eliminate the diverging national approaches to labelling of seeds, and, by replacing uncertainty with consistency, would provide clarity and confidence to industry, farmers and consumers.

What is needed are clear and practicable thresholds for labelling of seeds, in situations where there is an accidental presence in conventional seed of small traces of genetically-modified seed – known as "adventitious presence."

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.

Any discussion of adventitious presence inevitably turns upon some basic facts of plant breeding and seed production. This paper offers an overview of the relevant background, and an outline of what is at stake.

If you have specific questions or want more details, we will be pleased to assist you; you can contact the ESA General Secretariat by phone +32 (0)2 743 28 60 or e-mail (secretariat@euroseeds.org) and view more information on the ESA website at www.euroseeds.org.

Seed – the starting point of all food and feed

Seed makes food, feed and biological raw material for industrial uses. It is the starting point in an ever increasing value chain. While the global seed trade is valued at around €30 billion, the farm-gate value of harvested crops is already about €300 billion and the value of processed end product is estimated at about €3,000 billion. The 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 asset 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. It has been and still is the single most important factor in increasing crop yields and in raising the quantity and quality of agricultural production. With that, it has also provided the base for economic growth not only in agriculture, but also for the rest of the economy.

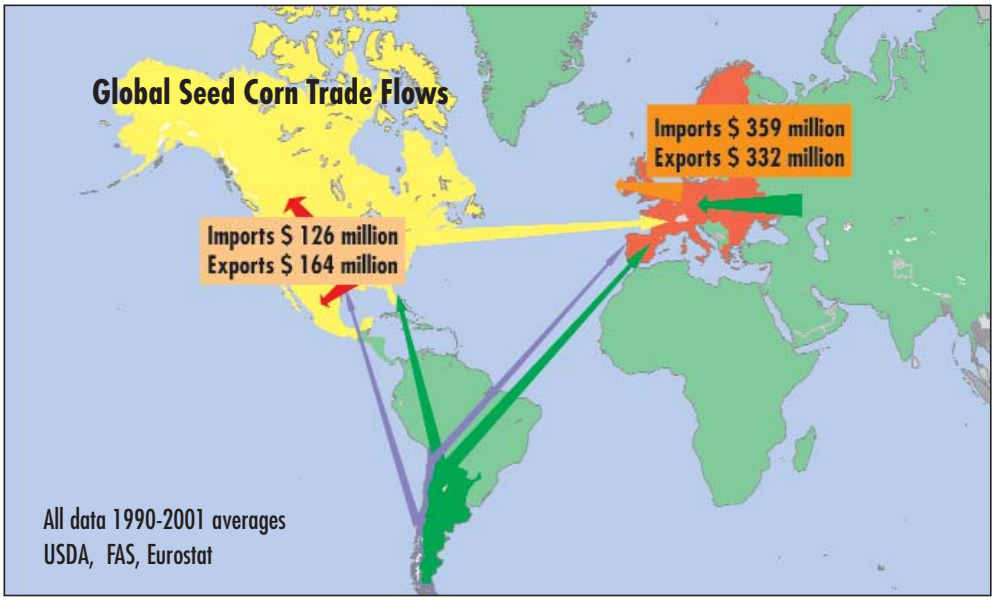
The development of an industry

To supply the needs of an expanding agriculture for quality seeds, a sophisticated plant breeding industry emerged over the past century. Its contribution to farming has been fundamental in the development of the modern industrial and service societies of today.

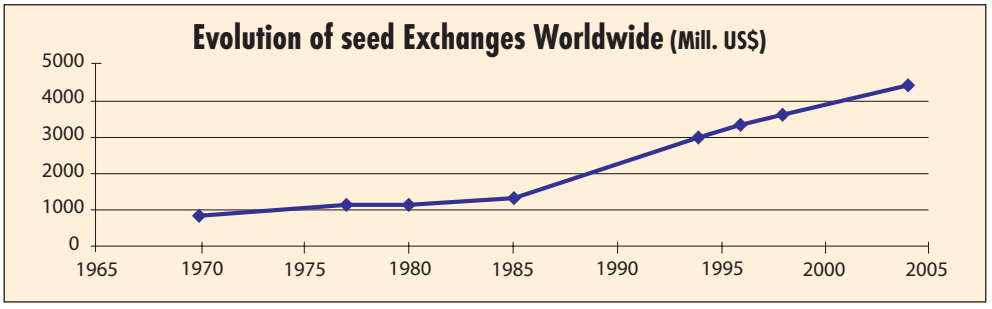
To meet different growing conditions (such as temperature, day length, soil quality, water availability) for growing a crop in different regions, and achieve the desired qualities for different end uses of the harvest (feed, food, industrial uses), plant breeders have developed large numbers of specific 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.

But Europe's seed industry is also highly international business, and seed companies use breeding and production facilities in both hemispheres, so as to have two growing seasons in one year. This winter production is a key factor in its competitiveness.



Today around 20% of the $30 billion global commercial seed market consists of imports and exports all around the world – the consequence of a long tradition of cooperation and of exchange of the thousands of crop varieties that have been developed.



International Seed Federation: Evolution in international seed trade, 1970 - 2004[1]

Adventitious presence

Adventitious presence – or technically unavoidable presence - may occur in all arable farming, and at any step in the production of seed or grain, or in processing of harvested product in the food/feed chain. It has always been a feature of conventional agriculture, and is practically inevitable. 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 levels of impurity in seed of a crop variety have therefore always been accepted – for instance seeds of other crops, or seed of plants of a different variety (known as "off-types"). To respond to this reality, international as well as European legislation has set thresholds to determine what are regarded as acceptable levels of adventitious presence.

Ensuring quality

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 the international seed exchange worldwide and in particular in Europe, where cross-border trade in seeds has become the norm in the EU's Common Market.

Seed rules and regulations

Today, seed sold to farmers in the EU must be "certified" – which means it has been officially tested by the responsible authorities to meet the legal quality requirements set by EU seed law.

These EU requirements are stringent. Only seed of varieties listed in the EU's Common Catalogue of Agricultural Plant Varieties may be sold and grown in the EU. Certified seed of a field crop variety must perform in the field as well or better than existing varieties. It must maintain established quality standards - such as varietal purity, avoidance of seed of other plant types, and absence of dirt. It must also meet minimum requirements for germination.

Varietal purity quickly became recognized as a key element in plant breeding and seed marketing legislation. For instance, while there is only one species of maize (Zea mays L.), there are thousands of "varieties" of this species listed in the EU's Common Catalogue of Agricultural Plant Varieties. This EU Common Catalogue for field crops lists 81 different crop types and thousands of varieties, e.g. over 1,500 varieties of sugar beet, 800 varieties of vegetable-oil-producing oilseed rape and more than 4,500 varieties of maize. Any of these maize varieties is distinguishably different from all other maize varieties - by law it must be distinct, uniform and stable (DUS) to be made commercially available to European farmers. The EU's Seed Marketing Directives then lay down the detailed requirements for seed certification and seed marketing on a crop-by-crop basis.

The Paris-based Organisation for Economic Cooperation and Development OECD manages an international seed scheme and maintains a catalogue of registered varieties from more than 40 countries. This aids plant breeders and seed producers in meeting the harmonized registration requirements of the countries participating in the scheme and thus is the base for international trade and exchange of plant material.

In Europe, the EU's Seed Marketing Directives lay down the standards for the certification of seed and establish thresholds for their varietal purity to be sold to farmers[iv]. The Directives specify the maximum adventitious presence of non plant material, seeds of other species, minimum germination levels and off-types on a crop by crop basis.

In the production of conventional seed, the adventitious presence of such off-type plants is detected visually, by trained inspectors. The detailed description of every variety of crop plant makes this possible, by inspecting flowering plants in grow-out trials, to determine whether all plants of the variety are distinct and uniform, and whether the required varietal purity levels are reached. For hybrid maize varieties, the historical development of the level of varietal purity has been well documented; the average level of impurities over the past years has been around 0.7%.

A new dilemma with new technology

Varieties developed using genetic modification 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 – in just the same way as off-types have long been found in conventional varieties.
Clearly, the widespread cultivation of GM crops in many non-European countries also increases the possibility of adventitious presence of these GMOs in the non-GM seed produced in these countries for export.

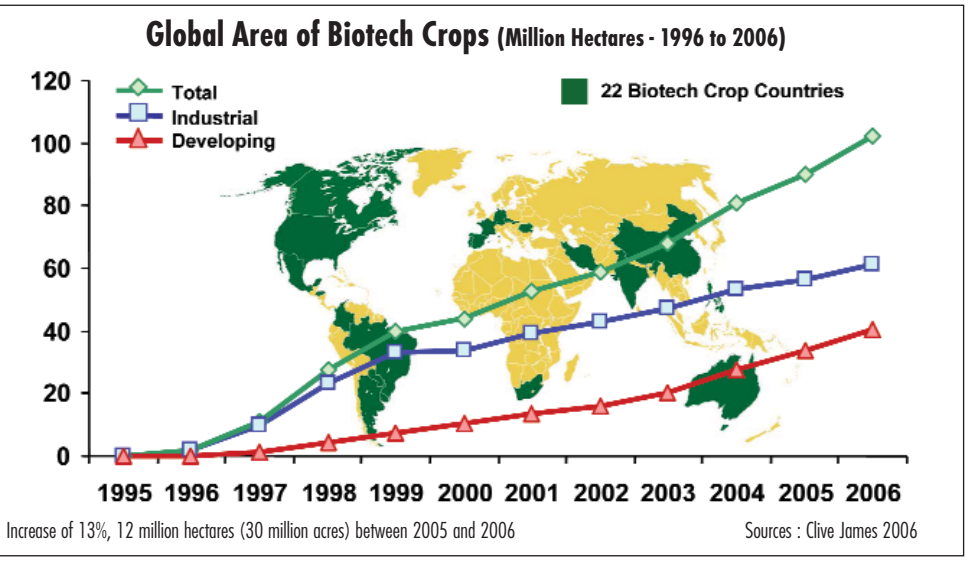
Striving for improved crop variety and seed quality

Early farmers would select the seed of those plants they had seen to perform best in their fields - hoping to see the same qualities reproduced in the next generation.
Modern plant breeding started with the increasing knowledge of the biology of crops and in particular with the discovery of Mendel's laws of genetics and inheritance. From that time on, it was possible to systematically select and breed for specific genetic expression. It was also the time when specialised plant breeding and seed production companies and seed growing farmers became established and started to supply the farming community with high quality seed.

The methods that have been at the disposal of plant breeders for centuries – selection and specific breeding – have been complemented over the last twenty years with new tools derived from rapid advances in biology and computing.

Development of new varieties can be speeded by molecular mapping and detection methodologies, the ability to read DNA code and genes and Marker Assisted Selection. The same technologies have enabled breeders to genetically modify crop plants, conferring genes with traits such as resistance to disease and insects that are not available in the plant's natural gene pool. This technique of genetic modification has been rapidly adopted worldwide except in the European Union.

The first government approved commercial GM varieties were released in 1996 following 10 years of extensive research and field testing, and since then there has been a rapid adoption by farmers around the world (notably also small-scale farmers in developing countries). Disease- and insect-resistant traits have improved food and income security, and new herbicide tolerant varieties of maize, oilseed rape and soybean have permitted better weed control and alternative management practices, including the adoption of minimum and zero tillage farming. Today, around 100 million hectares of GM crops are grown worldwide - more than double the acreage of all cereal crops in the EU.



Adventitious presence is not a safety issue

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

Setting thresholds at the right level

What is needed now in the EU is agreement on a common standard for adventitious presence of GM seed in non-GM seed.

Expecting an adventitious presence standard of "absolute zero" is neither realistic nor possible. Instead, what is required are thresholds that set clear levels and take account of the practicalities of seed production – including the widespread GM seed production and use in the rest of the world and in particular in seed production countries in the southern hemisphere.

Although there is currently little cultivation of GM crop varieties in the EU, observers of French seed production - which accounts for approximately 50% of EU hybrid maize seed production - have estimated that when GM maize grain is produced in the EU, 42% of French production would fail to meet a 0.5% threshold[v].

The EU's Scientific Committee on Plants came to a similar conclusion when evaluating seed threshold levels: "Achieving the 0.3% and the 0.5% thresholds will become increasingly difficult as GM crop production increases in Europe.[vi]"

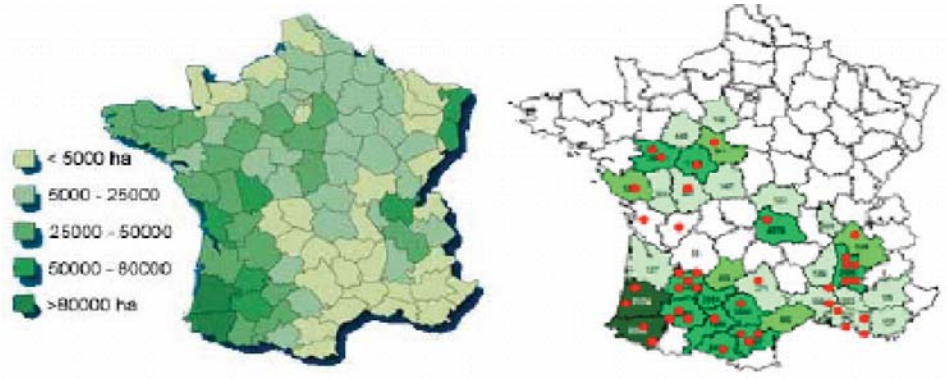
Since the visual examination used to identify off-types of conventional varieties may not reveal the presence of GM seeds, modern molecular detection tools are used, that can identify specific known DNA sequences, even at very low levels. Still, it would be inappropriate to fix a threshold at these low levels of detection. The Polymerase Chain Reaction (PCR) can already find very low occurrences of a specific DNA sequence amongst a huge mass of DNA, and may be able to detect even lower levels in the future. These PCR detection levels however do not correspond to the practical threshold levels set for impurities in conventional seed production.

The economic dimension

Establishing a practical threshold is of crucial economic importance for the seed industry and for farmers buying certified seed. The lower threshold levels are imposed, the higher the cost of production of the final seed product will be – and the more negative the impact on the competitiveness of seed production in the EU, currently the world's leading exporter of maize seed.

An excessively low threshold would drive costs up exponentially and could make seed production impossible for many growers and seed processors. Although isolation procedures can reduce the occurrence of adventitious presence, the availability of such "isolated" farmland for seed production will be a practical limitation – particularly in Europe. Total separation of designated seed production areas from general farming areas is also 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 where the highest intensities of commercial maize crop production can be found.

Coexistence in today's seed production



Maize crop production intensity

Maize seed production intensity
• seed production facilities

Source: Kalaitzandonakes, N., Univ. of Missouri, 2005 (publication in preparation)

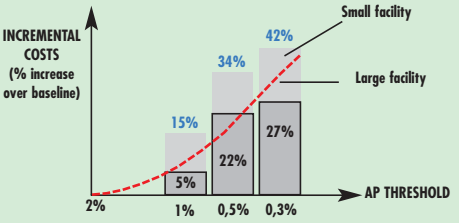
The costs of different labelling thresholds

Taking the production of hybrid GM maize seed as an example, there are four areas in the seed production process where costs increase as tolerance threshold levels for adventitious presence are lowered:

- Required increases in the isolation distance of the seed crop from neighbouring maize fields, increasing the number of 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;
- Harvesting the seed crops separately, ensuring more thorough cleaning of all machinery used in the various stages of harvesting, storage, seed cleaning and processing, perhaps using dedicated machinery;
- Testing each harvest of seed in the multiplication process to assess the presence, and level of adventitious presence of GM; and,
- Discarding seed that has adventitious presence levels above those determined to be acceptable.

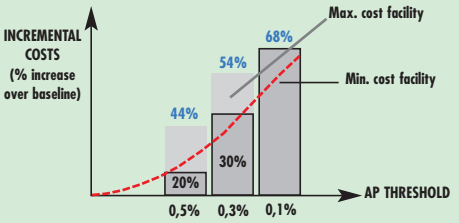
Empirical data provided by European hybrid maize seed producers for a study by Prof. N. Kalaitzandonakes of the University of Missouri has shown that setting a labelling threshold for GM adventitious presence at 0.5% would increase costs on average by 44% and at a level of 0.3% on average by 54%. Because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

COSTS OF THRESHOLDS FOR SEED - RESULTS FROM A STUDY IN THE US



Incremental costs for various AP thresholds (maize): Thecase of two representative facilities in the Midwest

COSTS OF THRESHOLDS FOR SEED - RESULTS FROM A STUDY IN THE EU



Incremental costs for various AP thresholds (maize): Empirical results from the EU

SEPROMA, the French Maize Seed Association, estimates 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 current confusion in EU law

The EU regulates the "deliberate release" of GMOs into the environment (through Directive 2001/18/EC). Amongst its many requirements, it states that any GM crop variety to be sold to farmers for cultivation in the EU must be assessed as safe. It also says that an approved GMO must be labelled and traced at all stages of placing on the market unless a threshold level is set below which such traces would not result in any labelling requirements.

At present, the GM Food and Feed Regulation[vii] has set a 0.9% labelling thresholds for adventitious presence of GMOs and derived materials in non-GM food and feed products. There are no thresholds for the presence of GM seed in non-GM seed – despite the fact that Directive 2001/18/EC allows for this[viii].

When it comes to **seeds, any** detectable adventitious presence of EU approved GM seed in non-GM seed must be labelled and traced, no matter how small that trace. While the food and feed industries benefit from a 0.9% adventitious presence labelling threshold, the seed industry has none at all! This not only imposes a heavy burden on the seed and farming communities; it is also misleading - crop varieties with only 1 GM seed in 10,000 seeds of non-GM varieties are clearly not GM varieties.

The erosion of the common market for seeds

Because no EU thresholds are established, some Member States have imposed or are in the process of setting their own, often extremely restrictive conditions on the seed industry. 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. But foremost, the major achievement of the EU's seed marketing Directives – the common market and free trade in seeds in Europe – is more and more being eroded. With different rules, 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, it is the European single market that is being denied to the seed industry and to farmers because of the failure to establish labelling thresholds.

CONCLUSION

Plant breeders and seed producers require:

The immediate establishment of clear and legally certain rules for the adventitious presence of trace amounts of approved GM material in non-GM seed lots.

Labelling thresholds for GM seeds that are adventitiously present in non-GM seed at levels which are practicably and economically achievable and which take account of different crop types;

Respect for other countries' freedom of choice, and avoidance of trade disruption in safe products, through establishing permanent allowances for the adventitious presence of GM material in imported non-GM supplies, once the exporting country has assessed the GM material as safe for health.

Respect for European farmers' and users' right to choose, by accepting the presence of trace levels of all GM materials that have been approved as safe.

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[i] http://www.worldseed.org/statistics.htm#TABLE%201

[ii] http://ec.europa.eu/food/plant/propagation/catalogues/common_catalogue_190706/index.html

[iii] See for instance http://europa.eu.int/eur-lex/en/consleg/reg/en_register_035040.html for a listing of consolidated texts on the Seed Directives

[iv] See for instance http://europa.eu.int/eur-lex/en/consleg/reg/en_register_035040.html for a listing of consolidated texts on the Seed Directives, and, http://europa.eu.int/eur-lex/en/consleg/main/2002/en_2002L0057_index.html for the consolidated text concerning seed of oil and fibre plants.

[v] 'Qualité : encore de très bons scores' - "Semences et Progres", Nr116, juillet, août, septembre 2003.

[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] Art 21.3 of Directive 2001/18/EC (as amended by Art. 30.2 of Regulation (EC) No 1830/2003 on traceability and labelling of GMOs) establishes a threshold level of 0.9% for the adventitious or technically unavoidable presence of GM in processed products.

[viii] See Art 21 of Directive 2001/18/EC The Deliberate release Directive.

About EuropaBio

EuropaBio, the European Association for Bioindustries, has 78 direct members operating worldwide, 12 associate members and 5 bioregions as well as 25 national biotechnology associations representing some 1800 small and medium sized enterprises involved in research and development, testing, manufacturing and distribution of biotechnology products.

About ESA European Seed Association

European Seed Association is the voice of the European seed industry. It represents the interests of those active in research, breeding, production and marketing of seeds of agricultural, horticultural and ornamental plant species. ESA has more than 30 national seed associations and more than 50 direct company members.

For further information, please contact :

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