IG Saatgut
Interessengemeinschaft für gentechnikfreie Saatgutarbeit

Protecting GM-free seed in the EU: Preventing GMO thresholds and respecting the zero tolerance policy

Background paper by IG Saatgut (Initiative for GM-free Seeds and Breeding)

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1. What are the issues?

The EU Member States, chaired by the European Commission, are discussing harmonising their official monitoring of the presence of genetically modified organisms (GMOs) in seed.[i]

According to EU law, a **'zero tolerance'** applies to seed: Seed lots contaminated with GMOs that have not been approved in the EU may not be marketed.[ii] Moreover, seed lots containing GMOs that are authorised in the EU must be labelled as genetically modified (**'labelling obligation'**).[iii] The EU Commission wants to weaken these provisions.

As part of the discussions regarding EU-wide harmonisation of seed control, the introduction of GMO labelling thresholds is being considered, as demanded by industry representatives.[iv] **Thresholds** would mean that by law, seed containing a certain level of GMOs would no longer need to be labelled as "genetically modified". For years, the European Commission has been trying to allow hidden contamination of seed in this way. The European Commission would also like to **end the zero tolerance policy**. This would mean that a certain presence of unauthorised GMOs in seed would be allowed if the amount contained remained below a certain threshold.[v]

Not least in view of free trade negotiations such as the TTIP negotiations[vi] and the Comprehensive Economic and Trade Agreement between the EU and Canada (CETA),[vii] the European Commission is once again attempting to implement these plans and to introduce "technical" thresholds and limits into the political process. This course of action is not new – the European Commission ended the zero tolerance policy for animal feed in 2011, justifying this as a harmonisation of official GMO testing.[viii]

Several EU Member States have infringed zero tolerance and the labelling obligation for GMOs in seed in recent years. They failed to intervene when seed lots contaminated with a certain level of GMOs were marketed without labelling, or when seed lots contaminated with non-approved GMOs were traded and sown.[ix] IG Saatgut warns that violations of the zero tolerance policy and labelling obligation, which are already impinging upon GM-free seed production, could become the accepted norm as a result of the introduction of thresholds in EU law and ending zero tolerance. Instead, the European Commission should fulfil its role as guardian of the Treaties and enforce adherence to the zero tolerance policy and labelling obligation among EU Member States.

The introduction of labelling thresholds or ending of zero tolerance would have severe, negative consequences for GM-free breeding and seed growing:

1. Thresholds or ending zero tolerance would **exacerbate the risk for seed producers that their seed is contaminated with GMOs.** It is expected that more contaminated seed lots would pass official controls without being removed from the market or labelled and be sown. Seed lots could be contaminated with GMOs unbeknown to the farmer sowing it, or to growers or breeders in the surroundings. Every field with cross-fertile species of crops at risk of GM contamination within distance of possible cross-breeding, as well as seed material that breeders and growers obtain from other sources would need to be considered even riskier than to date. Activities such as sharing machines with other holdings, storage, processing, and transport would be even more vulnerable to GM contamination. Yet possible damages that seed producers might suffer from GM contamination would not be covered by insurances.
2. Thresholds or ending zero tolerance would **increase the cost of GM-free seed production**. Increasingly sophisticated and expensive measures would be necessary in order to limit contamination risks. The resulting higher costs could threaten the existence of small companies.
3. Thresholds or ending zero tolerance could further **exacerbate the structural change from decentralised breeding and seed growing towards concentration in a few capital-intensive multinational companies**. Small-scale seed producers in local structures (i.e. growers, small-scale breeders, farmers saving seeds on their farm, seed production for self-supply, non-commercial conservation initiatives) could, eventually, be induced to give up seed production for the crops concerned. Increased contamination risks could hinder GM-free seed growing for concerned crops in entire regions.
4. The quantities of GM contamination detected in seed could increase in the medium run. Hence, it is likely that the thresholds introduced would need to be raised in order to adapt to rising contamination levels, leading to ever increasing GM contamination. In the medium term, thresholds or ending zero tolerance would lead to **increasingly widespread GM contamination and could spell the end of GM-free seed breeding and GM-free seed production.**

2. The discussion surrounding thresholds and zero tolerance – what are the arguments?

2.1. The introduction of thresholds and the end of the zero tolerance policy would create legal *un*certainty

Those in support of ending the zero tolerance policy and introducing thresholds argue that thresholds are necessary to create legal certainty for seed companies.[x] They argue that a threshold would save seed companies from high costs and liability cases, since it would mean that seed contaminated up to a certain level would no longer need to be recalled, and seed crops that are found to be contaminated after they are sown would no longer need to be destroyed.

IG Saatgut's assessment: Thresholds do not create legal certainty. Even if they were introduced, uncertainty would remain for seed producers regarding non-marketable lots. Under the new rules they would need to ensure adherence to the thresholds, which would require confirmation by potentially even more complex tests.[xi] And of course, this would take place under a higher risk of contamination: If

authorities no longer keep to the zero-tolerance policy and – below the threshold – the labelling obligation for GM content in seed, GM contamination would increasingly go unnoticed. Seed companies would then make less effort to avoid GM contamination in their seed, and the risk of contamination in GM-free seed would rise. Ultimately, controlling costs would increase, while preventive measures intended to protect against contamination would be even more limited.

IG Saatgut's position: Legal certainty is also important to the seed companies and organisations of IG Saatgut. A ban on the cultivation and experimental release of GMOs offers the greatest legal certainty. As long as this remains unimplemented, a stopgap solution is required at the very least: For crops exposed to a contamination risk, *every* seed lot must, without exception, be tested for the presence of GMOs consistently and *before* it is brought onto the market.[xii] This should minimise the risk of seed lots being recalled from the market, or of farmers having to plough up contaminated fields, which both result in damages and costs further down the value chain. The costs associated with testing, as well as costs that arise when contamination is discovered, must be borne according to the polluter pays principle, i.e. by those who create GM constructs and profit from their licences.

2.2. The effects of a 0.1% contamination level on fields

Supporters of thresholds argue that contamination of 0.1%, and even above this level, can be considered "traces", "negligible" or a "low level presence".[xiii]

IG Saatgut's assessment: Even contamination at these levels can have significant consequences. If a 40-tonne lot of maize seed were contaminated with GMOs at a level of 0.1%,[xiv] this could mean that 1,000 hectares are sown with GM-contaminated maize.[xv] On average, 100 genetically modified plants could then grow on every hectare.[xvi] Up to 50 million pollen grains could be produced during inflorescence by each genetically modified plant which could hybridise with other plants.[xvii]

If a 10-tonne lot of rapeseed were contaminated with GMOs at 0.1%, GM-contaminated seed could be sown on approximately 3,000 hectares.[xviii] On average, 500 genetically modified rapeseed plants could then grow on every hectare.[xix] Since rapeseed can produce approx. 50 to 100 billion pollen grains per hectare[xx], roughly 50 to 100 million GM pollen grains could be produced on every contaminated hectare.

The consequence would be the growing encroachment of contamination, which would lead to rising costs and uncertainty for seed companies in terms of complying with the applicable thresholds. This would sooner or later mean the end of GM-free seed production.

IG Saatgut's position: From their practical work in seed production, the seed organisations and companies of IG Saatgut know the actual meaning of the percentages that are being debated at the political level. They take the resulting contamination seriously.

2.3. Not a technical question – but a question of political responsibility!

Supporters of thresholds argue that the introduction of thresholds is justified because the results of laboratory tests on seed samples for GMOs are not fully reliable when it comes to detecting contamination below certain levels. They therefore call for "technical" thresholds, such as those the EU Commission would like to introduce.[xxi] The EU has already lifted zero tolerance for non-authorised GMOs in

feed in 2011, replacing it with a "minimum required performance limit" that allegedly defines what has been termed "technical zero".[xxii]

IG Saatgut's assessment: The following terms must be differentiated and understood:

- Statistical probabilities: When investigating whether a seed lot contains GMOs, it is only ever possible to test a part of the entire lot in a laboratory. There is therefore no 100% guarantee that if a lot is contaminated with GMOs, contaminated seeds will be duly found and detected in the sample taken from this lot. Only statistical probabilities can be calculated for this, based on the assumption that certain criteria for obtaining a representative sample[xxiii] are met. This means that in a sample of 3,000 grains from a maize seed lot, assuming that the lot is contaminated with GMOs at 0.1%, the statistical probability of detecting this contamination in the sample would be approx. 95%.

  This does not mean, however, that a contamination of a lot below 0.1% cannot be determined with samples of 3,000 grains. If a lot is, for example, 0.05% contaminated, from a statistical point of view this contamination will be detected with a probability of approx. 78%. The statistical probability of proof of contamination increases with the size of the samples (more seeds) that are taken from the lots and investigated.[xxiv]

- Limit of detection of the method: The question of statistical probabilities is often mixed up with the question of the limit of detection. For example, in the case of 3,000 grain samples in maize seed, a "limit of detection" of 0.1% is often mentioned.[xxv] But this can be easily misleading. The limit of detection of the method refers to the lower limit at which the presence of GM contamination can be detected in a sample using a specific method.[xxvi] What is critical here is that this limit is low enough to ensure that every single GM seed in a sample is detected by the laboratory.[xxvii] This is possible for accredited laboratories working diligently and with an appropriate testing plan for seed from crops such as maize, rapeseed and soybeans; limits of detection significantly below 0.1% are feasible here.[xxviii] If the test result finds GM material, this is reliable evidence that the lot is contaminated.[xxix]

IG Saatgut's position: If a GM seed is detected in a test sample, there is no technical reason for an official body not to label the affected seed lot or to simply tolerate illegal contamination. The political decision-makers are instead called upon to take political responsibility. Irrespective of the degree of contamination detected, it is their duty to implement applicable EU law, and therefore to implement the labelling obligation as well as zero tolerance of GMOs in seed.

The authorities of the German Federal States have been leading the way for some years: If GMOs are detected in seed, the affected lot is systematically withdrawn from the market. This works: GM contamination of maize seed is decreasing.[xxx]

Conclusions

The following steps are essential in order to preserve GM-free seed production as a cornerstone of GM-free agriculture and food production:

1. The European Commission and EU Member State governments need to swiftly enact a moratorium, or even better a ban, on the deliberate release and cultivation of GMOs in the European Union; they should stop any further authorisations of GMOs in Europe. The moratorium in Switzerland should be prolonged and extended in scope to cover also deliberate releases.
2. Decision-makers in the European Union and Switzerland need to implement the polluter pays principle. Those who developed the potentially contaminating gene constructs and hold the licencing rights to them need to bear the costs of ensuring GM-free production, both those costs now borne by GM-free seed producers and those of official controls. The polluter pays principle must apply to the entire food and feed production chains.
3. The EU Commission and EU Member States are called upon to ensure that the EU labelling obligation for authorised GMOs in seed and the EU's zero tolerance for non-authorised GMOs in seed are maintained.
4. The EU Commission needs to enforce the rigorous implementation of the labelling obligation and zero tolerance by EU Member States, including effective official controls *before* seed is marketed:
    - When contamination with non-authorised GMOs is detected, the seed lots concerned should be prevented from being marketed and destroyed;
    - When contamination with authorised GMOs is detected, the seed lots concerned should be labelled as GM according to EU law; if the seed is sown, all relevant information on the concerned surfaces should be recorded in a publicly accessible register;
    - The results of official controls for GMO presence in seed and detailed information about governmental measures to remediate any detected contamination with GMOs should be published completely and in due time before the cultivation season starts with sowing.

3. Protection of GM-free seed cultivation: future-proofing seed and food production

Seed is at the beginning of the food production chain. GM-free food production cannot be maintained if we accept a fundamental contamination of seed. There really is no alternative to zero tolerance in seed.

Whether or not we protect GM-free seed production will have an influence on the structures of our plant breeding, seed production and agriculture. IG Saatgut is convinced that GM-free seed is essential for the preservation of independent, on-farm seed cultivation and organic breeding, as well as the urgently needed restructuring of agriculture. Ultimately, it is a question of food and seed sovereignty.

Contact for further information: Stefanie Hundsdorfer, IG Saatgut, Policy Director, stefanie.hundsdorfer@ig-saatgut.de; more information on www.ig-saatgut.de

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[i] The European Commission initiated this discussion in the EU Regulatory Committee under the Deliberate Release Directive 2001/18/EC at the meeting on 14/12/2016, on the basis of the following report: JRC Technical Reports (2015): European Network of GMO Laboratories. Working Group "Seed Testing" (WG-ST), Working Group Report.

[ii] Art. 4 (1) Directive 2001/18/EC.

[iii] Art. 21 (1) Directive 2001/18/EC.

[iv] Cf. e.g. European Seed Association (2012): Position. Presence of EU-Approved GMOs in Seed; American Seed Trade Association and European Seed Association (2015); Transatlantic Trade and Investment Partnership Agreement (TTIP). Priority Issues for the Sector. Joint Statement.

[v] In political jargon and by the proponents of ending the zero tolerance policy, abolishing zero tolerance is also referred to as tolerating a "low level presence – LLP".

[vi] Cf. US: Article X.12, 8. (Global Low Level Presence Initiative), TTIP negotiation papers, Chapter Sanitary and Phytosanitary Measures, Consolidated Proposals, leaked on 02/05/2016.

[vii] Cf. Consolidated CETA text, published on 26 September 2014, Article X.03.

viii Commission Regulation (EU) No 619/2011 of 24 June 2011.

[ix] Cf. IG Saatgut (2012): Saatgut sichern – Schwellenwerte verhindern. Auswirkungen von GVO-Verunreinigungen im Saatgut auf die ökologische und konventionelle Saatguterzeugung (*Protecting Seed against GM Contamination. Impacts of GMO Labelling Thresholds and Ending Zero Tolerance in Seed – the Perspective of Organic and Conventional Seed Producers*); Central Science Laboratory (2007): Adventitious traces of genetically modified seeds in conventional seed lots: current situation in member states. Research tender ENV.B.3/ETU/2006/0106r.

[x] Cf. European Seed Association (2012): Position. Presence of EU-Approved GMOs in Seed.

[xi] If thresholds were introduced, authorities would need to quantify the amount of GM contaminants found during official inspections, in order to prove that they are above or below a certain threshold. This could, for example, be attempted using a quantitative polymerase chain reaction (PCR) or a larger test sample (more seeds) and/or a greater number of (partial) samples. The costliness of such a testing plan would depend on political decisions stipulating the accuracy required by the tests and the distribution of any risks arising from quantification errors between seed companies and consumers. Cf. Michael Kruse (2007): Gutachterliche Stellungnahme zur Gestaltung von Probenahmeplänen für einen Saatgutschwellenwert für gentechnisch veränderte Organismen (GVO) von 0,1% (*Expert opinion on the design of sampling plans for a seed threshold of 0.1% for genetically modified organisms (GMO*s).

[xii] In IG Saatgut's view, EU Member States should ensure that at least two samples are taken for GMO testing from every agricultural or horticultural species at risk of GM contamination, without exception and continuously before the seeds are brought onto the market. A sample of maize seed should contain at least 3,000 seeds. Furthermore, seeds which are certified abroad should be tested on import in the event that appropriate test certificates are not provided. It should be left to the seed growers and the companies that bring the seeds onto the market to decide whether they wish to have one of the two tests performed by independent, accredited laboratories and provide the authorities with proof of the quality and accuracy of the results, or whether both tests should be carried out by official authorities. The testing plans, as well as the methods of sampling and GMO detection, should be designed to guarantee the utmost care and use of state-of-the-art laboratory technology. It should be ensured that every seed that may contain genetically modified material in the sample is detected. Seed lots which are not supplied commercially, but instead are used or exchanged privately, should be exempt from the GMO testing requirement. Seed lots in these sectors are sometimes so small that sample sizes which make sense for GMO testing in the commercial sector would leave almost no seeds, or none at all, to be used.

[xiii] Cf. e.g. Bundesverband Deutscher Pflanzenzüchter (German Plant Breeders' Association) (2010): Position. Umgang mit GVO-Spuren im Saatgut regeln (*Regulating the handling of GMO traces in seed*.)

[xiv] 0.1% contamination in a seed lot (with reference to the number of grains) means 1 GM grain in 1,000 grains.

[xv] The calculation is based on the assumption that the thousand-seed weight is 400 grams and 100,000 maize grains are sown per hectare.

[xvi] It is assumed that the GM seeds contained in the lot are evenly distributed across the different hectares.

[xvii] Frieder Hofmann, Mathias Otto, Werner Wosniok (2014): Maize pollen deposition in relation to distance from the nearest pollen source under common cultivation – results of 10 years of monitoring (2001-2010), in: Environmental Sciences Europe 2014, 26: 24.

[xviii] The calculation is based on the assumption that the thousand-seed weight is 6.5 grams and 50 rapeseeds are sown per square metre.

[xix] It is assumed that the GM seeds contained in the lot are evenly distributed across the hectares.

[xx] Frieder Hofmann, Ulrich Schlechtriemen, Werner Wosniok, Mathias Foth (2005): GVO-Pollenmonitoring. Technische und biologische Pollenakkumulatoren und PCR-Screening für ein Monitoring von gentechnisch veränderten Organismen. (*GM pollen monitoring. Technical and biological pollen accumulators and PCR screening for monitoring GMOs*.) BfN Scripts 139. Bundesamt für Naturschutz (German Federal Agency for Nature Conservation), Bonn – Bad Godesberg.

[xxi] Bundesverband Deutscher Pflanzenzüchter (German Plant Breeders' Association) (2010): Position. Umgang mit GVO-Spuren im Saatgut regeln (*Regulating the handling of GMO traces in seed.*)

[xxii] Commission Regulation (EU) No 619/2011 of 24 June 2011; European Commission (2011): Questions and answers on the low level presence (LLP) of GMOs in feed imports, MEMO/11/451, Brussels, 24 June 2011.

[xxiii] Cf. Arbeitsgemeinschaft der Anerkennungsstellen für landwirtschaftliches Saat- und Pflanzgut (Working Group of the German Seed Certification Agencies) (2013): Probenehmer-Richtlinie. Probenahme, Kennzeichnung und Verschließung von Saatgut. (*Sampler guideline. Sampling, labelling and sealing seed*.)

[xxiv] The political discussion sometimes points out that increasing the samples would be too costly. It is true that the authorities (and ultimately taxpayers) and seed businesses incur costs when they examine seed for GMOs. IG Saatgut is also of the opinion that the cost burden on the general public for this technology, which is of no benefit to the majority of citizens, is unacceptable. This does not mean, however, that the tests should become less stringent. "Turning a blind eye" would only promote an undetected contamination of seed with GMOs. Instead, the polluter pays principle must be implemented to finance testing: Those who introduce GM constructs into the world and profit from their licences must bear the costs for systematic sampling and testing.

[xxv] Cf. e.g. JRC Technical Reports (2015): European Network of GMO Laboratories. Working Group "Seed Testing" (WG-ST), Working Group Report.

[xxvi] Where the limit of detection is set depends on the detection method used, particularly on the DNA quantity used in the polymerase chain reaction, as well as the genome size of the plant species.

[xxvii] Laboratories must bear in mind that seeds may not always be completely genetically modified but contaminated only with one of several sets of chromosomes. GMO detection should also capture these heterozygous contaminated seeds.

[xxviii] The limit of detection can be calculated with reference to the number of seeds or the number of chromosome sets in a sample.

[xxix] Diligent laboratories can rule out the possibility that non-replicable GM dust which is not classed as GMO and does not fall under genetic engineering legislation leads to false positive results.

[xxx] http://www.greenpeace.de/sites/www.greenpeace.de/files/publications/maissaatgutverunreinigungen_2016_tabelle_20160419_0.pdf;
https://www.greenpeace.de/sites/www.greenpeace.de/files/publications/20140414_maissaatgutverunreinigungen_tabelle_0.pdf