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# Harmonised Monitoring of the GMO Content in Seeds

Guidance document of the Working Group on Genetic Engineering of the German Federal Government and the Länder (LAG)<sup>1</sup>

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## Foreword

Effective enforcement of the law on genetic engineering in the German federal states with respect to seeds and planting material depends not only on the implementation of uniform standards for sampling, sample preparation and the analysis and assessment of laboratory results, but also on the reliable exchange of information between the involved authorities and the companies whose seed lots are being sampled.

In 2006, the conference of environment ministers recommended the use of a first guidance document in the federal states (circular resolution no. 9/2006).

At its 47<sup>th</sup> session on 20-21 May 2014, the LAG decided to examine the existing guidance document, which had last been revised by resolution of the 40<sup>th</sup> LAG session on 26-27 October 2010, and to verify whether it is still up to date and to revise it, if necessary.

The present new version was recommended for use by the conference of environment ministers and their circular resolution no. 15/2015.

## 1 Sampling strategy for maize and oilseed rape

The following were identified as relevant criteria for the sampling of seeds (maize and oilseed rape) to test for GMO content:

1. the time-point and location of sampling
2. the sampling technique used
3. the size of the test sample

Consequently, depending on the origin of the seeds, different strategies are needed for

- the sampling of seeds in parallel with the certification procedure in Germany and
- the sampling of seeds which has already been certified.

As a general rule, the results of monitoring for GMO content of seeds should be made available to the authorities and to the relevant companies before sowing begins. The later the authorities and companies in question receive information regarding GMO content in conventional seeds, the greater the effort required to trace and, if necessary, recall individual units of seeds. The aim is to avoid having to enforce measures after contaminated seeds or planting material has been sown.

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<sup>1</sup> <http://www.lag-gentechnik.de>

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## 1.1 Sampling of seeds in parallel with certification in Germany

To ensure that samples are taken at the earliest possible date, sampling should be carried out in parallel with seed certification. The advantage is that sampling can be conducted at the beginning of the distribution chain (“bottleneck”) so as to avoid having to invest greater effort in sampling in the subsequent stages of distribution (wholesaler/central warehouse → retailer → farmer). The advantages can be summarised as follows:

- The seeds can be sampled and analysed at an early stage, i.e. before delivery to the retailer and hence also before sowing.
- For the seed companies, this means that potential product recalls can be avoided.
- Any other official orders arising from § 26 GenTG can be implemented before further placing on the market (§ 3, No. 6 GenTG) or before sowing takes place.

Hence the LAG proposes the following procedure for the sampling of seeds processed in Germany:

Sampling of seeds which is to be certified in Germany should primarily be conducted in parallel with the certification process. Co-ordination with the certification agency is therefore advisable. Sampling is conducted by an authorised sampler and in accordance with the current guidelines for samplers<sup>2</sup> issued by the Working Group of the German Seed Certification Agencies. Basically, all seed material intended for sowing can be included in the monitoring scheme. At least 10% of the lots presented for certification should be routinely sampled for analysis of GMO content. It is irrelevant thereby whether one is dealing with so-called re-fastening, that is, seed lot numbers with a “W” supplement or lots in the “normal” certification procedure. Samples are selected according to the principle of randomness. A risk-oriented selection of samples may be warranted under certain circumstances.

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<sup>2</sup> Working Group of the German Seed Certification Agencies: “Guidelines for samplers: seed sampling, labelling and fastening”; <http://www.ag-akst.de>

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## **1.2 Sampling of certified seeds**

A significant portion of maize and winter oilseed rape seeds traded in Germany is certified outside Germany and thus cannot be sampled as described under point 1.1. above. In addition to conventional distribution via wholesalers, seeds are partially sold directly to customers. Since the distribution channels differ depending on the variety, it is not possible to make general recommendations about the sampling location.

Basically, it here deemed to be valid that the results of monitoring for GMO content in seeds should be available to the authorities and to the companies in question before sowing begins. It is recommended that the sampling takes place as early as possible. Since seeds that are certified (outside Germany) are initially delivered to the central storehouses of breeding companies (seed companies) and commercial retailers, the sampling should take place at these places. These central storehouses are frequently operated by logistics service providers (usually haulage companies). Direct contact to the breeding and trading companies is recommended, not only to identify the locations of the central storehouses but also to determine the current seeds availability in the stores. Experience has shown that the companies are happy to provide the required information. Where seeds are sold directly, sampling may also be required at the end of the supply chain (on the farm) in exceptional cases. The number and selection of sampled seed lots depends on the particular circumstances in that federal state. In order to avoid duplicating the analyses unnecessarily, only one sample from each seed lot should be tested in the context of the official seed monitoring.

## **1.3 Representativeness/homogeneity of samples**

The representativeness and homogeneity of the sample are to be ensured in accordance with the sampler guideline mentioned in point 1.1. above. That guideline contains accepted criteria for designing sampling plans to obtain representative seed samples.

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## 2 Sample preparation and analysis

LAG recommends that the GMO analysis be performed in parallel with the seed lot approval process. The analysis, including the size, processing and splitting of samples etc. follows the official collection of methods for sampling and analysis of samples published by the German Federal Office for Consumer Protection and Food Safety (BVL) in accordance with § 28b GenTG and within the scope of the monitoring of genetic engineering work, of contained-use facilities, of deliberate releases and placing on the market of GMOs.

The central document is the official procedure G 30.00-2 "Detection of genetic modifications in seeds – examination procedure" in accordance with § 28b GenTG. This procedure describes the required size of laboratory samples and the sample preparation method. The G 30.00-2 procedure is based on the concept for seed analysis for genetically modified plant content issued by the LAG sub-committee for method development in 2006.

## 3 Sampling and analysis of other crops

During routine testing of seeds for GMO content, particular emphasis is placed on the crop species maize and oilseed rape. Thus, at present, the likelihood of GMOs occurring in conventional seeds and the risk of spreading in the environment is adequately taken into account. Samples are/were also taken to a lesser extent but at regular intervals from mustard, soybean, sugar beet and potato crops. Furthermore, other crop species are sampled and analysed on a random basis (spot checks) or as the situation demands. The sampling strategy and methods of analysis used for maize and oilseed rape should be followed as closely as possible when sampling the seeds of other crop species. In the process, crop-specific particularities in the supply chain must be taken into consideration.

### 3.1 Sampling of seed potatoes

A concept for the official control of seed potatoes for genetically modified admixtures was developed by LAG and tested over three years of cultivation. The resulting "Concept for the regulatory monitoring of seed potatoes for admixtures of genetically modified components" [see Annex] is recommended for use in the federal states as needed. Because the test plan is specially recommended for seed potatoes, the detection limits deviate from those for other crops. Note that the concept is only suitable for seed potato production which takes place

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exclusively in Germany and is subject to the local official monitoring scheme. The concept is not applicable to deliveries of seed potatoes from other EU countries and third countries.

### **3.2 Sampling of soybean seeds**

Due to the current practice of inoculating soybean seeds with rhizobia and the very short lifespan of these rhizobia after application, soybean seeds do not reach the market until just before sowing. If the certification of the seeds takes place in Germany, sampling can be carried out prior to inoculation, as described in 1.1. However, inoculated soybean seeds are normally imported into Germany only shortly before sowing. In order to ensure that monitoring takes place as early as possible, the local competent authority should carry out the sampling at the premises of the wholesaler importing the seeds. Sampling at the end of the supply chain is generally not recommended because farmers are required to place their orders in advance and the seeds are delivered directly to them.

### **3.3 Sampling of sugar beet seeds**

Sugar beet seeds are delivered directly to the sugar factories by the breeding companies just before sowing. They are responsible for distributing the seeds to farmers on the basis of advance orders. Sampling should therefore be carried out by the seed certification agencies or even earlier in the manufacturing process at the relevant seed companies. The requirements concerning the representativeness of the sample and the method of analysis (§ 28b method) correspond analogously to the sampling strategy described under point no.1.

## **4 Exchange of information**

### **4.1 During sampling**

The companies being monitored should be informed of the purpose of the sampling by the official samplers at the time of sampling. The affected companies are advised to inform the German Plant Breeders Association (BDP) of the sampling. The email address of the BDP can be obtained from the LAG office. The competent authority should inform the sampled company of the results of the analysis without delay. The sampled lots should not any longer be placed on the market until information about a conclusive negative test result has been received.

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## 4.2 Between the federal states

A web-based seed monitoring data base (*SGM-Datenbank*) developed by the BVL serves as a central source of information for the federal states in the area of monitoring for GMO content in seeds. It is therefore recommended that the data sets for sampled seed lots be created in the data base directly after sampling – i.e. before beginning the analysis. In the case of sampling seeds which have not yet been finally processed, the data set should be created before further placing on the market. In their personal profile, users can subscribe to receive an automatic notification for samples with the test result “GM detected” when the status of the sample is set to “public”. If seeds of an affected lot are found to have reached another federal state, then that state should be informed immediately by the state which carried out the analysis.

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## Annex:

### ***Concept for the regulatory monitoring of seed potatoes for admixture of genetically modified components***

The concept is based on two co-ordinated phases which are tied to the sub-processes of potato planting stock production. It makes use of the existing routines and work sequences used in the certification of planting stock and plant health controls.

Phase 1: Official field inspection for varietal purity.

Phase 2: Official laboratory analysis of seed potatoes for admixture of genetically modified components

#### **Phase 1: Official field inspection for varietal purity**

As part of the approval procedure, field inspections consisting of a number of rounds (at least 2) are carried out by specially trained field certifiers or inspectors of the competent authorities of the federal states. They visually inspect the stock for varietal purity (“foreign varieties and variant types”) and other criteria. Field certifiers receive instruction regarding the test method and their objective. The aim of these training sessions for field certifiers is to ensure that the potato varieties can be distinguished with a high degree of probability. Plots exhibiting foreign varieties and variant types will be documented.

#### **Phase 2: Official laboratory analysis of seed potatoes for admixture of genetically modified components**

Samples for GMO analysis shall be taken only from seed production areas that contain foreign material. 10 % of seed production areas with detected foreign material should be examined for the presence of genetically modified components. Inspection for quarantine pests is mandatory and without alternative for all proposed propagations. In the federal states, seed potato fields will be sampled in a uniform manner by the plant protection service of the competent authority. The legal basis for this and the test methodology are set out in two EU directives and in one national regulation. For every 3 hectares of a production project, a sample of 200 tubers is taken from the inactivated stock or during storage. The samples are prepared for analysis for quarantine bacterioses in the laboratory of the official plant protection service and used for PCR analysis of *Clavibacter michiganensis ssp. sepedonicus* (CMS) and *Ralstonia solanacearum* (Smith) Yabuuchi *et al.* (RS) as well as the analysis for the potential presence of genetically modified organisms. The laboratory must be equipped with accredited or creditable PCR test methods for CMS, RS and genetically modified potatoes, e.g. EH92-527-1 (Amflora).