



Prevention of contamination of imported Bio Suisse approved products with GMOs

Bio Suisse information note

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1 Aims of this information note

This information note will help you to assess the risk of inadvertent mixing of organic products with genetically modified organisms (GMOs) or genetically modified material derived from GMOs (hereinafter termed GM material) in imported products and to comply with Bio Suisse requirements. You will find information on

- legal requirements,
- Bio Suisse requirements,
- indications of how inadvertent mixing of genetically modified and organic products can be avoided.

Further information on legal requirements, Bio Suisse requirements regarding imports, and measures to avoid inadvertent admixture of GM material are available on the Bio Suisse website, under the heading "GMO" These include the following information regarding GMOs:

- Information note on "Bud without genetic engineering" (German and French)
- Interpretation of the ban on genetic engineering
- Form for confirmation of freedom from GMOs (from infoxen site, also available in English)
- Information note on "GMO-critical food and feed components" (German and French)

The organic sector is trying to avoid GM material at all levels of production. The cost of these measures is borne by the organic sector at present. Bio Suisse endeavours to enforce the polluter-pays-principle regarding the inadvertent mixing of GM material and organic products at all levels of production. Nevertheless it must be assumed that the aims of organic production are ignored in many countries and that organic producers themselves must be vigilant in order to avoid inadvertent admixture of GMOs or GM material.

2 Organic farming and genetic engineering: the general principles

Organic foods around the world are produced without the use of genetic engineering. This is congruent with the identity and values of organic producers and companies and it is what consumers expect.

The Swiss legal requirements for organic production (Swiss Ordinances SR 910.18 and SR 910.181) also prohibit the use of GMOs and GM material on organic farms and in the production of organic foods. This prohibition equally extends to organic products produced in accordance with the EU Organic Regulation (EC 834/2007). Non-organic ingredients in organic products (SR 910.181 List C, Annex 8 of the detailed rules for implementation of EC 889/08), feeds and imported products must similarly comply with these requirements (SR 910.181).

Inadvertent mixing of organic products and GMOs or GM material can occur during production because organic farming does not operate in a vacuum! Due to drift from neighbouring fields (e.g. pollen) and inadvertent admixture during harvest, transport or processing, a residual risk of contamination remains.

While non-organic products may contain such admixtures up to a level of 0.9% without having to declare the fact, such threshold values can not simply be applied to Bud products. Bio Suisse's aim is that no or only the slightest traces of GMOs or GM material will be found in organic products. This includes imported raw materials and processed products marketed under the Bud label in Switzerland.

With its requirements, Bio Suisse ensures that – intentionally and verifiably – no genetic engineering is used in production and processing! Compliance with these Bio Suisse provisions is checked using a tight and independent inspection system.

Therefore, organic products may be marketed in Switzerland using the indication "*ohne Gentechnik hergestellt*" ("produced without genetic engineering") as they are the only products which meet the stringent requirements of food law with regard to this indication. The indication "*gentechnikfrei*" ("GM-free") is not compliant with Swiss law but is used in some EU countries (Austria, Germany).

3 Legal requirements

It is important for importers¹ of raw materials or auxiliary inputs to be used in the organic sector to know the basic legal requirements of working with GMOs.

The basic legal requirements include:

- Swiss Ordinance on genetically modified foodstuffs (SR 817.022.51)
- Swiss Ordinance on GMO feed lists (SR 916.307.11)
- Swiss Ordinance on the production and marketing of feedstuffs (SR 916.307)

3.1 Foods

Only GMOs or GM material approved by the Swiss Federal Office of Public Health (BAG) may occur in foodstuffs. These currently include soya, maize, Vitamins B2 and B12 as well as chymosin².

The Swiss Ordinance on genetically modified foodstuffs (VGVL SR 817.022.51) prescribes that foods containing more than 0.9% GM material (DNA, protein) in the raw material must be labelled as "genetically modified". This designation and the organic label are mutually exclusive in the whole of Europe.

The 0.9% tolerance level only applies to GMOs approved in Switzerland. Products containing traces of up to 0.5% of GM material which is not approved in Switzerland are assessed by the Swiss Federal Office of Public Health on a case-by-case basis. Hence it is worthwhile to use careful chain-of-custody monitoring with a view to eliminating the risk of market withdrawal.

3.2 Feeds

Only GMOs or GM material approved by the Swiss Federal Office of Public Health (BAG) may occur in foodstuffs. As for feeds, these currently include soya, maize, and Vitamin B2³.

The Swiss Ordinance on the production and marketing of feedstuffs (SR 916.307) prescribes that feeds containing more than 0.9% GM material must be labelled as "genetically modified". The 0.9% tolerance level only applies to GMOs approved in Switzerland. Feeds containing traces of up to 0.5% of GM material which is not approved in Switzerland are tolerated by the Swiss Federal Office for Agriculture.

Imported raw materials for feedstuffs such as maize cob meal, maize gluten or extracted soya bean meal are treated separately by the Federal Office for Agriculture. Marketable products are listed in GMO feed list I and may contain any GM maize or GM soya variety approved in the EU. The Federal Office for Agriculture also maintains a list of dietetic feeds and additives (GMO feed list II). At present (July 2009) the list does not contain any products, but the old approval for Vitamin B2 is still valid.

¹ Compliance with the Swiss Ordinance on Organic Farming is a prerequisite when importing organic products to Switzerland. Two different scenarios must be distinguished:

- Products imported from a country on the List of Countries (Argentina, Australia, Costa Rica, EU Member States, India, Israel, New Zealand).
- Products imported from any other country.

² Approved foodstuffs as of July 2009: GTS 40-3-2 Round-up-Ready Soya; BT176 Maize; BT11 Maize; Mon810 Maize

³ Approved feedstuffs as of July 2009: GTS 40-3-2 Round-up-Ready Soya; BT176 Maize; BT11 Maize; Mon810 Maize

4 Bio Suisse requirements regarding the prevention of contamination with GM material in imports of raw materials

With its Bud label, Bio Suisse has established a high quality standard for organic products. When products are imported that are approved by Bio Suisse, the requirements of the Swiss Ordinance on Organic Farming must be met at all times and importers must be able to document that the Bio Suisse requirements have been met all the way from the field to the buyer in Switzerland and that this is confirmed by the inspection/certification body⁴.

Imported organic products are tested for GMOs and GM material and moreover the measures taken to avoid contamination of the organic products with GM material are assessed. More specifically this means that in the case of sensitive products such as maize, maize gluten, rapeseed (and mustard as a close pollination partner of rapeseed) and soya all import batches are checked by Bio Suisse. If GM material is found in a batch, all persons involved in the supply chain must provide evidence showing that they comply with Bio Suisse requirements and have exercised their duty of care. If this evidence is not available, Bio Suisse reserves the right to stop a batch, even if the residues do not exceed the legal threshold value of 0.9% GM material in the raw material. Details and examples are listed in Table 1.

The avoidance of additives and enzymes produced by GMOs in closed systems presents a special challenge. In the final product the genetic modification of the product can not be detected, the situation regarding the need for authorization in the EU is unclear, and it is not expected that there will be an obligation to label such products in the EU. However, since these substances are rarely used in the organic sector the problem can be contained and currently concerns only vitamins.

Table 1: Compilation of products of different GMO statuses and different uses in the organic sector using the example of soya

Raw material	GMO status	Use in the organic sector
Genetically modified (GM) soya	Swiss authorization for the GM construct used is available. Soya is labelled " <i>gentechnisch verändert</i> " ("genetically modified").	*Not approved in the organic sector
Lecithin from GM soya beans	Swiss authorization for the GM construct used is available. Lecithin is labelled: " <i>aus gentechnisch veränderter Soja</i> " ("from genetically modified soya").	*Not approved in the organic sector
Up to 0.1% GM soya in organic soya (0.1% is considered the	Labelling not required, accompanying documentation shows the GM soya content or this is ascertained by own	✓ Tolerated in the organic sector if it can be shown that admixture was technically unavoidable or

⁴ As an importer of organic products which you wish to place on the market as Bud products you need the following:

- a licence contract with Bio Suisse with the relevant appendix, and import approval;
- a product approved by Bio Suisse, or an approved supplier (all companies involved, from production to export, must be approved by Bio Suisse);
- if need be an individual authorization by the Swiss Federal Office for Agriculture (FOAG)

As an importer of organic products which you wish to place on the market as Bud products you need the following for each delivery:

- a "Certificate of inspection for the import of products from organic production" as issued by the exporter's/producer's certification body;
- a quantified Bud label product approval issued by Bio Suisse ("Bud" stamp) on the certificate of inspection.

You can find more information on the general provisions for imports on the Bio Suisse homepage under the heading Import/Export.

detectability threshold) in the crop as taken from the field (new Standard 2.1.14 as of 1 May 2009).	analysis. Swiss authorization for the GM construct used is available.	inadvertent and if all Bio Suisse requirements were met.
Up to 0.9% GM soya in organic soya in the traded product or final product	Labelling not required, accompanying documentation shows the GM soya content or this is ascertained by own analysis. Swiss authorization for the GM construct used is available.	✓Tolerated in the organic sector if it can be shown that admixture was technically unavoidable or inadvertent and if all Bio Suisse requirements were met.
Organic chocolate with lecithin from non-organic soya beans	No labelling and no accompanying documentation showing that the lecithin has been produced from GM soya.	✓Allowed in the organic sector if confirmation of freedom from GM is available. Form is at www.bioxgen.de or www.infoxgen.com

The following section lists measures to avoid GM material. Operations approved by Bio Suisse must comply with these measures. In individual cases Bio Suisse may determine additional mandatory conditions or refrain from requiring compliance with individual conditions. These conditions ensure that GM material does not inadvertently enter Bud products, that consumers can trust organic products and that the measures taken will safeguard the added value of organic products.

5 GMO risk products and countries

Every year, Bio Suisse assesses the GMO production situation in individual countries. Based on this assessment, critical crops and countries are identified and tests are solicited accordingly. At present, samples from every imported batch of soya, rapeseed/mustard and maize are tested for GMOs if the produce originated in a country which is considered critical on account of either extensive cultivation of GM crops in those countries or because of unclear information⁵. In 2009 the following countries were concerned: Egypt, Argentina, Australia, Brazil, Bolivia, Burkina Faso, Chile, China, Honduras, India, Canada, Colombia, Mexico, Paraguay, Philippines, Poland, Portugal, Romania, Slovakia, Spain, South Africa, Czech Republic, Uruguay, USA⁶.

5.1 Requirements upon analytics

The analysis for GMO contamination is the final link in a company's quality assurance chain. Protein tests are less suited to the low detectability limits required in the organic sector than PCR. Regarding these analyses particular attention should be paid to the following:

- Selection of a proven laboratory (ask the inspection body).
- For qualitative PCR analyses the detection limit of the analytic equipment must be at least 0.03% (35S promoter) or 0.01% (NOS terminator) respectively.
- The quantitative analysis method should have a detectability limit of 0.1%.
- Sampling should be done in such a way that samples are as homogeneous as possible for each batch⁷.

Documentation to be submitted to Bio Suisse

- Description of sampling method
- Laboratory and analysis method used
- Analysis results

⁵ See also the information note on "GMO-critical food and feed components".

⁶ This information concerns crops sown in 2009. In Bulgaria, France and Germany GMOs were only grown in trials and not for the market in 2009.

⁷ Details on representative sampling and analysis can be found at http://www.bioxgen.de/documents/bxg_V5_3-4_050823.pdf

- Detection limit of the analytic equipment used
- Certificate of inspection and delivery documentation (lot number). The analysis must be clearly correlated with the delivery note/certificate of inspection!

5.2 Risk of admixture and preventive measures

Below you will find the Bio Suisse requirements regarding the avoidance of contamination with GM material. Bio Suisse approved operations must comply with the requirements and should observe the recommendations. In individual cases Bio Suisse may impose additional mandatory requirements or lift certain conditions.

5.2.1 Seed propagation

Bio Suisse conditions

The quality assurance measures listed under the following points also apply to the production and processing of seeds.

Bio Suisse recommendations

- Test the source material
- Only produce (organic) seeds in GM-free regions/countries.
- Where fodder beet or sugar beet seed or seed potatoes are produced, the distances to be kept to GMO plots of the same crop as listed in Table 3 are to be increased by a factor of 100.

5.2.2 Production

The organic farmer must be in a position to demonstrate measures taken to avoid contamination with GM material (duty of care). These depend on (i) the crop and (ii) the proportion of GM crops grown in the region, (iii) the physical distance to fields containing GM crops, and (iv) topographic and meteorological characteristics. The different individual situations will be discussed below.

If a neighbouring farmer grows genetically modified crop plants of the same species as the organic producer, this must be considered a special risk situation and may render the production of the organic crop impossible. Therefore, it must be ascertained at sowing time whether a neighbouring holding is producing genetically modified crops. The production of an organic crop in a field directly adjacent to a genetically modified crop is not permitted.

Bio Suisse conditions for farmers producing in a country where genetically modified crop plants are cultivated

- It must be shown where genetically modified crops are grown and which crops are grown.
- Organically propagated seed must be used subject to availability.
- If the use of non-organic seed is permitted, a declaration by the seed trader assuring that the ban on the use of genetic engineering has been complied with must be available⁸.
- Avoid third party seeders or clean thoroughly prior to use.
- Waiting periods for plots on which GM crops were previously grown (Table 2).
- The harvested crop must not contain more than 0.1% GMOs (new Standard as of 1 May 2009).

Table 2: Waiting periods in the case of new plots on which GM crops had previously been grown. These are also subject to the general Bio Suisse conditions for conversion.

⁸ Upon request, the seed trader must be able to prove that

- the seed was grown in GM-free areas or observing sufficient minimum distances to the nearest field with GM crops respectively;
- quality assurance systems (ISO or HACCP) are applied during harvest, crop cleaning, and transport;
- samples are regularly tested for GMO residues.

Crop	Waiting period	Rationale
Maize	Local differences; not necessary in Central and Northern Europe, otherwise 2 years.	Potential for volunteer crops emerging and introduction into the wild in certain regions.
Rapeseed	15 years where volunteer crops are not controlled. 2 years where volunteer crops are controlled in a targeted manner.	Seeds of rapeseed can lie dormant for a long time (15 years). Frequent volunteer rapeseed in fields and on field margins.
Soya	2 years	
Cotton	2 years	

Bio Suisse conditions for farmers subject to GM crops grown within a 4 km radius

Individual measures taken must be documented, and specifically

- it must be shown where genetically modified crops are grown and which crops are grown;
- organically propagated seed must be used subject to availability;
- if the use of non-organic, non-dressed seed is permitted, a declaration by the seed trader assuring that the ban on the use of genetic engineering has been complied with must be available⁹;
- minimum distances as outlined in Table 3 must be kept to fields in which genetically modified crops are grown.

In consultation with Bio Suisse, minimum distances may be revised downwards only if

- the organic plots are large;
- the sowing time significantly diverges from that of the GM crop;
- material harvested from the marginal rows (in wind-pollinated crops such as maize) is processed separately;
- the organic plots are geographically well delimited/separated;
- seed not containing GM material is available;
- the farmer growing the GM crop(s) reliably takes measures to avoid contamination;
- third party seeders are avoided or thoroughly cleaned prior to use.

Table 3: Safety distances between organic and GM crops aiming at limiting contamination to less than 0.1%.

Crop	Safety distances between GM plots and organic plots
Maize	500 m
Potatoes	10 m
Rapeseed	4000 m for male sterile varieties 600 m for male fertile varieties
Soya	100 m

Bio Suisse recommendations

- Only purchase seed from GM-free regions/countries.
- Purchase seed from traders who do not offer GM seed of the same crop.
- Keep a reference sample of the seed.
- Only use seeders used exclusively on organic holding.
- If seed is saved for the following crop, regularly test own seed for freedom from GMOs.

⁹ Upon request, the seed trader must be able to prove that

- the seed was grown in GM-free areas or observing sufficient minimum distances to the nearest field with GM crops respectively;
- quality assurance systems (ISO or HACCP) are applied during harvest, crop cleaning, and transport;
- samples are regularly tested for GMO residues.

5.2.3 Cropping

Bio Suisse conditions

All auxiliary inputs used (fertilizers, plant protection products etc.) must be approved for organic farming (authorization by the inspection body, FiBL and OMRI lists of approved substances must be at hand).

5.2.4 Harvesting

The risk of contamination is high with harvesters, since it is almost impossible to thoroughly clean such machines. Even following large segregation batches residues may remain. If own harvesters are used the risk of contamination is negligible. In cases where machinery is shared in a machinery syndicate or where a contractor carries out harvesting, special measures are necessary as outlined below.

Bio Suisse conditions for contractors/machinery syndicates working in a region where GM crops are grown

Where third party machinery¹⁰ is used it must be shown that,

- the machine has been thoroughly cleaned before use, that the organic crop was harvested first, or that the machine was thoroughly cleaned prior to use and a GM free crop was harvested prior to the harvesting of the organic crop;
- that the crop was transported to the collection point in a cleaned transporter/transport container.
- Get the contractor to confirm that these measures have been taken.

Bio Suisse recommendations

- Use harvesters/transporters exclusively used on organic holdings.

5.2.5 Collection, transport, storage

Each time a shipment is reloaded there is an additional risk of contamination (residues in reloading plant, contamination of the transport container, human error). Using strict and documented segregation of organic, non-organic and GM produce, inadvertent admixture can largely be avoided.

Bio Suisse conditions for collection points, buyers, exporters

- Collection points and exporters of Bio Suisse products require a Bio Suisse licence/approval.
- Containers for collection and transport must be thoroughly cleaned (three prior loads to be certified). Additionally, the containers must be lined with plastic sheeting.
- Overseas/rail shipments in containers solely used for organic cargo.
- In addition to the shipping documents a GMO analysis is required.
- Staff training on the contamination problem.

Bio Suisse recommendations for collection points, buyers, exporters

- Special time slots for deliveries of organic products.
- Clearly demarcate access to organic silo.
- Reserve reloading sites exclusively for organic products.
- Use of closed transport containers (containers, big bags, bags) from the harvest site to the Swiss border or beyond.
- Use of closed transport containers used exclusively for organic products, from the collection point onwards.
- Keep reference sample from each delivery.
- Use separate storage rooms exclusively for organic products (ideally this should include loading and unloading devices).

¹⁰ See also the FiBL information leaflet on risks associated with the use of third-party machinery.

5.2.6 Processing

Processing and storage plants (mills, cleaning installations, reloading systems) have a high risk potential. Temporal separation may not always be the best solution. A field study in a mill in Switzerland has shown that even following thorough cleaning and very large segregation batches, GMO residues were still being found in the organic flour. Therefore, the aim in processing should be physical separation, i.e. processing should not involve non-organic or GM material. This is of particular concern with regard to processing aids, additives, and enzymes.

Bio Suisse conditions for processors and exporters

- Processors of Bud products require a Bio Suisse licence/approval.
- Strict spatial separation of organic and GM products must be guaranteed in storage and processing.
- Where temporal separation is used, thorough cleaning and a generous segregation batch is mandatory.
- Organic produce must be the first batch to be processed.
- In the case of approved processed products with a risk potential, the supplier must, at the point of delivering the goods, present a declaration assuring that the ban on the use of genetic engineering has been complied with (form from www.infoxgen.com).

Bio Suisse recommendations

- Only buy products from suppliers who verifiably strive to avoid GMOs.
- Process organic products in installations reserved exclusively for organic products.
- No processing of organic products in companies which also process GM products.
- Regular GMO analyses.