



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. Here you will find information on

- the legal requirements,
- Bio Suisse requirements
- information sheet needed by Bio Suisse for confirmation of GMO prevention
- 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 "Bud without genetic engineering" (German and French)
- Interpretation of the ban on genetic engineering
- Form for confirmation of freedom from GMOs (Infoxgen-Form)
- Information note "GMO-critical food and feed components"

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 for handling GMOs

It is important for importers¹ of raw materials or auxiliary inputs to be used in organic farming 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 B12² and Chymosin.

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 careful chain-of-custody monitoring is advisable with a view to eliminating the risk of "market withdrawal".

3.2 Feeds

Only GMOs or gm material approved by the Swiss Federal Office for Agriculture (FOAG) may occur in feedstuffs. As for foods, these currently include soya, maize, and Vitamin B2 and Vitamin B12³.

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

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

² Approved foodstuffs as of August 2011: GTS 40-3-2 Round-up-Ready Soya; BT176 Maize; BT11 Maize; Mon810 Maize

³ Approved feedstuffs as of August 2011: 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 organic farming
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 organic farming
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 organic farming if it can be shown that admixture was technically unavoidable or

⁴ As an importer of organic products which you wish to market as Bud products you need the following: a licence contract with Bio Suisse with the relevant appendix, and import approval; both product and supplier must be approved by Bio Suisse (all firms involved from field to export must be Bio Suisse approved);

If need be, an individual authorization by the Swiss Federal Office for Agriculture (FOAG)

As an importer of organic products which you wish to 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 home page 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 organic farming if it can be shown that admixture was technically unavoidable or inadvertent and if all Bio Suisse requirements were met.
Lecithin from non-organic soya beans	No labelling, no accompanying documentation showing the lecithin has been produced from GMO soya.	➔Allowed in organic farming but not as Bio Suisse approved chocolate! Lecithin only allowed as organic lecithin for coating.

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 cannot be detected, the situation regarding the need for authorization in the EU is unclear nor is the labelling of such products expected to be made compulsory in the EU.

The following section lists measures to avoid gm material. Producers and processors 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. In 2010/11 the following countries were concerned:

Egypt, Argentina, Australia, Brazil, Bolivia, Burkina Faso, Canada, Chile, China, Colombia, Costa Rica, Czech Republic, Honduras, India, Mexico, Myanmar, Pakistan, Paraguay, Philippines, Poland, Portugal, Romania, Slovakia, Spain, South Africa, Uruguay, USA⁵.

The situation is unclear in the former Soviet states. GMO analyses are required for gm-critical products imported from this region.

Crops grown as gm varieties are: cotton, potato, pumpkin, lucerne (alfalfa), maize, papaya, rapeseed, soya, tomato, sugar-beet. All these crops are grown in the USA.

The situation is quite different in the other regions with GMO production: outside the USA the gm-critical crops are soya (South America), maize (South America and Europe) and rapeseed (Canada).

Huge amounts of gm soya and maize are grown, stored and traded worldwide. Therefore the risk of contamination and commingling has risen and we demand a PCR-Analysis of each import of bud approved soya and maize. For rape and sugar beet a PCR is necessary if the product was grown in a critical country. See Table 5 for detailed analyses requirements for bud approved products.

6 Chain-of-custody documentation requirements

Here you will find the Bio Suisse requirements regarding the avoidance of contamination with gm material together with our recommendations. Bio Suisse approved producers and processors must comply with the requirements and should observe the recommendations: this must be documented. In individual cases Bio Suisse may impose additional mandatory requirements or lift certain conditions.

6.1.1 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 GMO-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.

6.1.2 Production

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

If a neighbouring farmer grows genetically modified crop plants of the same species as the organic producer, this presents a special risk situation and may render the production of organic crops 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 gm crop plants are cultivated

- ☐ A map showing where genetically modified crops are grown and which crops.
- ☐ Document stating organically propagated seed used, subject to availability.
- ☐ If the use of non-organic seed is permitted, a declaration that the ban on the use of genetic engineering has been complied with must be available.
- ☐ If external seeders used: declaration of thorough cleaning prior to use.
- ☐ For plots on which gm crops were previously grown (Table 2): confirmation of the waiting periods
- ☐ When the harvested crop is brought to the collection point the PCR or protein test must not show 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.

Crop	Waiting period	Rationale
Maize	Local differences; not necessary in Central and Northern Europe, otherwise 2 years.	Potential for volunteer crops emerging and overgrowing in regions with mild winters (southern.Europe)
Rapeseed	15 years where volunteer crops are not controlled. 2 years where volunteer crops are controlled in a targeted manner.	Rape seeds hardy, can lie dormant for a long time (15 years). Frequent volunteer rapeseed in fields and on field margins.
Soya	2 years	
Cotton	2 years	

Reduction of distances only in consultation with Bio Suisse, if

- the organic plots are large (5 ha and more)
- for maize: sowing time must diverge from gm crops by 3 weeks, confirmation required
- the organic fields are geographically well delimited/separated (by woodland, lakes or rivers, in valley)
- seed without gm material is available; test results required
- only privately owned seeders and harvesters are used
- GMO analyses to be submitted before delivery to collection point.

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

Crop	Safety distances between GMO 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 GMO-free regions/countries.
- Purchase seed from traders who do not offer GMO seed of the same crop.
- Keep a retention sample of the seed.
- Only use seeders used exclusively on organic holdings.
- If seed is saved for the following crop, regularly test own seed for freedom from GMOs.

6.1.3 Cropping

Bio Suisse conditions

All auxiliary inputs used (fertilizers, crop 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).

6.1.4 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 GMO crops are grown

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

- the machine has been thoroughly cleaned before use, the organic crop was harvested first, or that the machine was thoroughly cleaned before use and a GMO-free crop was harvested prior to the harvesting of the organic crop. Cleaning certificate required.
- that the crop was transported to the collection point in a cleaned transporter/transport container.
- Cleaning certificate required.

Bio Suisse recommendations

- Use harvesters/transporters exclusively used on organic holdings.

6.1.5 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 for each critical batch (For table, see Appendix)

Bio Suisse recommendations for collection points, buyers, exporters

- Special time slots for deliveries of organic products.
- Staff training on the contamination problem
- 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 retention sample from each delivery.
- Use separate storage rooms exclusively for organic products (ideally this should include loading and unloading facilities).

6.1.6 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. Test runs must be made to quantify residues. Where organic produce and non-organic products with GMOs are processed simultaneously total separation of the installations and lines should be achieved.

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.

Processing should not involve GMOs or gm material. This applies in particular to auxiliary processing inputs, 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 at www.infoxen.com). (Table 4)

Table 4: Non-organic additives and ingredients approved for Bio Suisse processing and which need to be certified as without use of genetic engineering

Product Group	Infogen form to be presented for non-organic products
Fruit and vegetable products, fruit juices	lactic acid (E270), citric acid (E330), acidifying cultures, pectin degrading enzymes
Bread, cakes and pastries	amylase, hemicellulases, pure vegetable fats and oils, citric acid (E330), tartaric acid (E334), for baking powder vehicles
Syrups	amylases, lactic acid (E270), citric acid (E330)
Wine and sparkling wines Fruit wines	cultured yeast and bacteria starter cultures, pectinases, tartaric acid (E334)
Spirits	cultured yeast, lactic acid (E270), enzymes
Vinegar	cultured yeast, pectinases
Soya products	<i>Aspergillus sojae</i> , <i>Pediococcus halophilus</i> , <i>Saccharomyces rouxii</i>
Yoghurt and cream products	yoghurt, sour milk & kefir cultures, yeast, pectin, lactic acid bacteria
Cheese	rennin & rennin substitutes, lactic acid, wine lees (smear cultures)
Sausages	lactic acid. starter cultures, sodium citrate
Baby food/first food	Vitamin B2
Non-ruminant food	Vitamin B2, B12

7 Analytic requirements

- The analysis for GMO contamination is the final link in an enterprise's quality assurance chain. Protein tests
- are less suited to the low detectability limits required in organic farming than PCR, so a PCR should be done.
- With these analysis particular attention should be paid to the following:
- Selection of a proven laboratory (ask the inspection body)
- An ELISA protein test will provide adequate evidence. For imports into Switzerland a quantitative TaqMan PCR must be presented.
- For qualitative PCR analyses the detection limit of the analytical 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%.
- The method of sampling should ensure that the samples of each batch are as homogeneous as possible. ⁶
- Minimum sample amount for maize, soya and rapeseed is 10000 grains.
- With a result of 0.01% and more the gm plant/event must be accurately identified.

Documents to be submitted to Bio Suisse

- Description of sampling method and sample amount
- Laboratory and method of analysis used
- Analysis results
- Detection limit of the analytic equipment used
- Certificate of inspection and delivery documents (lot number). The analysis must clearly correlate with the delivery note/certificate of inspection!

Should the PCR be positive, Bio Suisse must be informed so that it can be decided whether or not the product is marketable.

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



Table 5: Compilation of the requirements for analytics and chain-of-custody documentation for imports

GMO Analysis				
Import		PCR/ELISA		Information
Soya	Organic soya in feedstuffs and foodstuffs – whole or ground – in composite products (origin of soya must be known)	Analysis required for all imports	35 s and NOS Proof of soya	<ul style="list-style-type: none"> - PCR; Chain-of-custody documentation – Certification of organic seed: USA, Canada, Mexico, Argentina, Brazil, Paraguay, Uruguay, South Africa, Honduras, Costa Rica, EU – If use of non-organic seed is allowed, the seed trader must be able to prove the seed was grown without use of genetic engineering
	Organic lecithin	Contains negligible DNA, so PCR alone not decisive.		<ul style="list-style-type: none"> – PCR/ELISA results, if available – Organic certification
	Non-organic soya products such as Tocopherol, non-organic lecithin	Contain negligible DNA, so PCR alone not decisive.		<ul style="list-style-type: none"> – Infoxgen form and PCR, if available
Maize	Organic maize – whole grain or ground – in composite products – in feedstuffs as grain, bran, meal fodder, seedcake and gluten	Analysis required for all imports	Proof of maize Proof of 35 s and NOS	<ul style="list-style-type: none"> – PCR – Chain-of-custody documentation – Organic seed certificate: for USA, Canada, Mexico, Argentina, Brazil, Bolivia, Paraguay, Uruguay, Costa Rica, Honduras, South Africa, Egypt, Philippines, EU – If use of non-organic seed is allowed, the seed trader must be able to prove the seed was grown without use of genetic engineering
	Dextrose, glucose, starch	Contains negligible DNA, so PCR not meaningful		Certificate for organic starch/organic dextrose/organic glucose

GMO Analysis				
Import		PCR/ELISA		Information
Maize ff	Approved non-organic and organic maize gluten	Analysis required for all imports	Proof of maize Proof of 35 s and NOS	– PCR results – Infoxgen certificate
Rapeseed	Organic rapeseed – whole grain or pressed – in composite products – in feedstuffs als grain, pressed seedcake	Analysis required for all imports from USA, Canada, EU <u>Spot check</u> on imports from Chile, China, Japan	Proof of rapeseed Proof of 35 s and NOS If result positive, identification of the event	– PCR – Chain-of-custody documentation – Organic seed certificate: for all countries also needing a PCR
	<i>No non-organic rapeseed products allowed</i>	-	-	-
Sugar-beet	Organic sugar-beet	<u>Spot checks</u> on imports from USA or Canada	Proof of rapeseed Proof of 35 s & NOS	– Organic certification
	Molasses from non-organic sugar production	<u>Spot checks</u> on imports from USA, Canada	Proof of sugar-beet Proof of 35 s & NOS	– Infoxgen certificate for molasses – PCR results
Flax seed	Whole grain flax seed for foodstuffs and feedstuffs	<u>Analysis required for all imports</u> from Canada or the USA	Proof of linseed Proof of T-NOS and npt II If result positive, proof of event with T-NOS 95 bp.	– Organic certification
Potato	Organic potato for foodstuffs and feedstuffs	PCR not necessary		– Organic certification
	Non-organic potato protein	PCR not necessary		– Infoxgen certifikate