Practical guidelines: How to avoid GMOs contaminations

For farmers, food & feed processors

IFOAM EU GROUP

MAKING EUROPE MORE ORGANIC

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The practical guidelines are based on the following documents:
BÖLW, 2012, Praxishandbuch "Bio-Produkte ohne Gentechnik"
FNAB, 2009, Guide de bonnes pratiques concernant les OGM à destination du producteur.

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1 Introduction

In the 1990's, first GMOs were marketed in the USA and the EU. In parallel, were developed some legal frameworks to regulate those new organisms[1].

From the very beginning, the Organic Sector has taken a strong position: GMOs and their derivatives have no place in organic food and farming systems. This position, in the light of the four organic principles (Care, Ecology, Health, Fairness), was expressed in private standards, then in the European organic Regulation in 2007.

Today, organic agriculture is GMO free per definition[2]. This characteristic is important for both consumers of organic products and the Organic Sector. This claim means that GMOs are not deliberately or knowingly used and that organic producers take steps to avoid contamination. Although, organic could not be a claim of absolute freedom from contamination[3]. According to the Organic Regulation, organic products are guaranty GMO-free under 0,9% per ingredient[4].

Indeed, risks of contaminations are still high in Europe, even though 17 countries and 4 regions opted out GMO cultivation on their territory[5]. As soon as GMOs are cultivated (mainly in Spain) or released on the market, it poses a threat to non-GMO production. Without those national restrictions of GMO authorisations, the situation would be more difficult for GMO-free production, if not impossible[6]. Hence, the best way to avoid contamination and costs related to coexistence is to limit authorisation of GMOs in its different uses (cultivation, feed, transformation…).

To remain GMO-free according to its standards and not to undermine consumers trusts, the Organic Sector must take measures to avoid contamination at all steps of the production chain, from seeds to the final product. Despite the principle polluter pays principles[7], sectors that refuse to use GMOs have to take costly measures to avoid contamination.

With new genetic engineering issues, organic production is even more at stake. It would be impossible to avoid contamination, if no detection methods are available. That is notably why IFOAM EU welcomed the decision of the European Court of Justice that recognised in July 2018, that new genetic engineering techniques are GMOs and must be regulated as such, and calls the European Commission to make sure this decision is fully implemented in all Member States[8].

In order to facilitate the ability of the Organic Sector to remain GMO-free, IFOAM EU with the Organic Research Centre, has provided those guidelines to identify measures to be taken at each steps of the production chain. Those guidelines are notably based on the actualised and translated version of two documents from BÖLW[9] and FNAB[10], in order to give a larger access to such recommendations.

After an overview of the different legal texts to consider regarding organic farming and GMOs, the guidelines will provide specific recommendations to farmers and food & feed processors.

[1] Council Directive of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (90/220/EEC).
[2] Article 9.1 Council Regulation (EC) No 834/2007 and Article 11.2 Regulation (EU) 2018/848.
[3] IFOAM Organics International, Position Paper 'Genetic Engineering and Genetically Modified Organisms', 2016.
[4] Article 4 Council Regulation (EC) No 834/2007 and Article 5 Regulation (EU) 2018/848.
[5] https://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en.
[6] IFOAM EU, Socio-economic impacts of GMOs on European agriculture, 2017.
[7] Article 191, Treaty on the functioning of the European Union.
[8] IFOAM EU, press release 'IFOAM EU welcomes the European Court of Justice decision that new genetic engineering techniques will be regulated as GMOs'.
[9] BÖLW, 2012, Praxishandbuch "Bio-Produkte ohne Gentechnik".
[10] FNAB, 2009, Guide de bonnes pratiques concernant les OGM à destination du producteur.

2 GMOs and organic agriculture

2.1 Principles of the Organic Agriculture

In 2016, the International Federation of Organic Agriculture Movements (IFOAM) reaffirmed that the use of GMOs was not compatible with organic farming and that GMOs and their derivatives have no place in organic food and farming systems[11]. This position was reinforced in 2017[12]. Subsequently all organic regulations around the world prohibit the use of GMOs in organic products, as they are in stark contrast to the philosophy of organic farming and the four principles of organic agriculture:

- **The Principle of Health** – This Principle is about serving the wholeness and integrity of living system at various levels at various levels (immunity, resilience, regeneration, sustainability). The implication for breeding is that useful organisms need to be robust, dynamic, and resilient, able to benefit from interactions with the surrounding biome in which they grow, and to reproduce themselves and to produce high quality, nutritious food. This means that breeding needs to develop multilevel approaches, such as decentralized breeding for regional adaptability and enhancing genetic diversity and adapt organism to the environment instead of the environment to the organism.
- **The Principle of Ecology** – This principle in organic agriculture, is about contributing to optimally functioning of a diversity of site-specific ecological production systems. This means that breeding needs to develop multilevel approaches, such as decentralized breeding for regional adaptability and enhancing genetic diversity and adapt organism to the environment instead of the environment to the organism.
- **The Principle of Fairness** – This principle is about serving equity, respect, justice and stewardship of the shared world. It implies the need to develop new socio-economic structures in breeding to ensure free access to genetic resources, no patents of life, breeding approaches that involve all value chain actors, equal benefit sharing among chain partners, and maintenance and accessibility of diversity for future generations. Decisions regarding the authorization of GMOs should be subjected to a rigorous, democratic, and transparent assessment of the technology through participatory processes that include decision-makers from every area of society and every group of people who will be impacted by the technology.
- **The Principle of Care** - Organic agriculture should be managed in a precautionary and responsible manner to protect the health and wellbeing of current and future generations and the environment. This principle must be the main guide for all research, experimentation and release of GMOs.

2.2 Basic EU legislation on GMOs

Regarding GMOs and organic agriculture, different legal texts need to be considered: the Organic Regulation, the basic text on general Food Law and the GMOs legislation.

2.2.1 Organic regulation

The Council Regulation (EC) No 834/2007 contains the general objectives and principles for all stages of the production, processing and distribution of organic products and their controls. It also regulates the labelling requirements and advertising of organic products. The requirements of the EC Organic

[11] IFOAM OI, Position Paper: Genetic Engineering and Genetically Modified Organisms, 2016.
[12] IFOAM OI, Position Paper: Compatibility of breeding techniques in organic systems, 2017.

Regulation are specified by the EC Organic Implementing Regulation 889/2008. Therefore, the two EC Organic Regulations 834/2007 and 889/2008 must be considered together.

The EC Organic Regulation contains a general ban on the use of GMOs for organic production and sets out the basic requirements for proof of compliance with the ban on use (Article 4 (iii): '*exclude the use of GMOs and products produced from or by GMOs with the exception of veterinary medicinal products*').

The new organic regulation, Regulation (EU) 2018/848, adopted in 2018, and which will enter into force in 2021, confirms the incompatibility between organic agriculture and the use of Genetically modified organisms (GMOs) (Article 5 (iii): '*exclude the use of GMOs, products produced from GMOs, and products produced by GMOs, other than veterinary medicinal products*).

2.2.2 General Food Law

Regulation (EC) No 178/2002 on the general principles and requirements of food law contains the essential requirements for food and feed safety for all EU companies concerned. It contains the basic definitions of food law and regulates the primary responsibility of the companies involved in food and feed safety.

2.2.3 Legislation on GMOs

Directive (EC) 2001/18 on the deliberate release into the environment of genetically modified organisms, is the main text on GMOs. It provides a frame to regulate GMOs at the European level. The directive was completed by two regulations.

Regulation (EC) No 1829/2003 on genetically modified food and feed states that GMOs that can be used in food or animal feed and the food and feed derived therefrom may only be placed on the market if they are authorized throughout Europe in accordance with the Regulation. The authorized GMOs and the scope of the authorization (use as food or feed, cultivation) are published in the EU Register of authorized GMOs. The Regulation also lays down labelling schemes for food and feed which are supplied to the final consumer. Accordingly, food and feed must be labelled with an indication of genetic modification if it or its constituents contain GMOs or are made from GMOs.

The Regulation (EC) No 1830/2003 on the traceability and labelling of genetically modified food and feed contains appropriate labelling rules for food and feed before distribution to final consumers. It also contains specific rules on the traceability of genetically modified food and feed.

According to the labelling scheme, GMOs and ingredients and ingredients derived therefrom must be labelled in the course of the production or production of food and feed, even if the use of GMOs in the end product is not analytically detectable. Exceptions exist however for traces with a portion of up to 0.9% per ingredient, as far as these traces are coincidental or technically unavoidable (Article 7, Regulation 1830/2003 and article 21. 3 Directive 2001/18).

2.3 In organic agriculture, what is forbidden and what is allowed?

The EC Organic Regulation (834/2007 and 848/2018) prohibits for organic agriculture the usage of:

- GMOs,
- Products produced from GMOs,
- Products produced by GMOs.

As food, feed, processing aids, plant protection product, fertilizer, soil conditionner, seed, vegetative propagating material, microorganism or animal.

2.3.1 Principle: ban of the use of GMOs in organic production

The general principles of organic production include, except for veterinary medicinal products, no use of GMOs and products derived from or through GMOs and this is enshrined in EU law by the EC Organic Regulation (Whereas (9), Regulation 834/2007 and Whereas (23) Regulation 848/2018). Therefore, GMOs and products derived from or by GMOs may not be used as food, feed, processing aids, plant protection products, fertilizers, soil conditioners, seeds, vegetative propagating material, microorganisms or animals in organic production (Article 11, Regulation 834/2007 and Article 9, Regulation 848/2018).

When the first European legislation was adopted in the 90's, one techniques of genetic modification was marketed: transgenesis. But since then, different techniques of genetic modification were developed, and their legal status had been in the middle of a fierce debate in the EU. In 2018, the European Court of Justice clarified the scope of Directive 2001/18 (C-528/16)[13] confirming that organisms obtained from new genetic engineering techniques '*with no long record of safety*', are GMOs within the meaning of the GMO Directive and therefore come within the scope of the GMO directive. This decision means that all new techniques are GMOs and must be included in the scope of the GMO legislation. Therefore, products derived from or by them are prohibited by organic regulations. But it is crucial for the organic sector that no products from these new techniques of genetic modification are marketed until detection methods are available.

Organic products and the use of genetic engineering are mutually exclusive. If a product must be labelled with a reference to GMOs, in accordance with the general labelling provisions, it must not be labelled as an organic product at the same time.

2.3.2 In practice, what is forbidden in organic?

- GMOs

The use of GMOs is prohibited from organic agriculture. To understand the scope of this ban in organic agriculture, it is necessary to consider the definition of GMOs in the European GMO legislation and its scope.

'Genetically modified organism' is defined in Article 2 of Directives 2001/18/EC:

[13] ECJ, *Confédération Paysanne and others*, C-528/16, 25 July 2018.

"*genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination"*.

Article 3 and Annex I. B of Directive 2001/18 gives precision on the scope of the directive: '*mutagenesis*' and '*cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods*'.

The final decision on the legal status of new genetic engineering techniques[14] of the European Court of Justice also gives clarity on how to interpret the European GMO legislation:
"*Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive and in the light of recital 17 thereof, must be interpreted as meaning* ***that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive.***". In other words, new genetic engineering techniques with no '*long record of safety*' are included in the scope of the Directive.

IFOAM Organics International clarified the compatibility of different breeding techniques with organic agriculture and criteria to decide which techniques are compatible and which are not[15].

- Products produced from GMOs

Produced <u>from</u> GMOs means derived in whole or in part from GMOs but not consisting of GMOs or containing GMOs (Article 2, u, Regulation 834/2007, Article 3, 59 Regulation 848/2018) (example: oil made from GM soya, see below Table 1). **They are not allowed in organic production.**

The decisive factor here is whether the food or feed contains a substance produced from the genetically modified source material. It is irrelevant whether the material contains genetically modified DNA or proteins produced by the genetic modification. Therefore, products can be made from GMOs even if this cannot be (analytically) verified: for example, refined oil or Lecithin from genetically modified plants (soybean). If shredded plant material (meal, leaves) or pollen from genetically modified plants are not already classified as GMOs, because of the DNA contained therein (see above), they are made from GMOs.

Food and feed, which were only made with the help of a genetically modified processing aid are not produced from GMOs. Therefore, products derived solely from animals fed with genetically modified feed or treated with genetically modified medicinal products are not derived from GMOs. According to this, meat, milk and eggs are not made from GMOs if the animals from which they came are only fed on genetically modified feed. **None the less, such ingredients are not allowed in organic production, as GMOs are not allowed for feed.**

Products made from GMOs in food and feed must be labelled.

There are exceptions for accidental and technically unavoidable traces of products produced from GMOs in food and feed (see 2.3.3).

[14] ECJ, *Confédération Paysanne and others*, C-528/16, 25 July 2018.
[15] IFOAM OI, Position Paper: Compatibility of breeding techniques in organic systems, 2017.

- Products produced by GMOs

Produced by GMOs means derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs (Article 2, v, Regulation 834/2007, Article 3, 60 Regulation 2018/848) (example: vitamin produced by GM bacteria, see below Table 1). **They are not allowed in organic production.**

These include vitamins, flavors, rennet substitutes or other substances produced using genetically modified microorganisms.

The legal definition limits the classification of products as produced by GMOs. It depends on the last reproductive organism in the manufacturing process of the substance. Thus, starting from the product, the processing chain is considered backwards only up to the last living organism (for each ingredient). If this organism is not a GMO, the substance may be used in organic food and feed production. This means, for example, for enzymes that have been produced by microorganisms that it is only important that the microorganism was not a GMO. **It is irrelevant if the microorganism was fed with a nutrient solution containing substances produced from GMOs, such as soya lecithin from genetically modified soya, as long as the nutrient solution is not contained in the final product.**
This limitation is required for practical reasons. If GMO-derived substances need to be obtained from conventional sources (see 2.3.3), manufacturers can guarantee that they will not use genetically modified microorganisms. However, nutrient solutions have not yet been produced in GMO-free quality.
Conventional products produced by GMOs do not yet have to be labelled with an indication of this type of production. It is then necessary for organic operators to ask for GMO-free guaranties when they purchase products potentially concerned.

- Prohibited uses

The use of GMOs or products made from or by GMOs is prohibited as food, feed, processing aids, plant protection products, fertilizers, soil improvers, seeds, vegetative propagating material, micro-organisms or animals (Article 11, Regulation 834/2007 and Article 9, Regulation 848/2018)**.**

Foodstuffs are all substances or products intended or reasonably expected to be ingested in processed, partially processed or unprocessed state by humans. These include all substances intentionally added to the food during processing or processing.

Animal feeding stuffs are substances or products, whether additives, whether processed, partly processed or unprocessed, intended for oral animal feed.

Processing aids are substances that do not remain in the finished product and therefore themselves are not food or feedstuffs. In organic production, the use of such substances should be minimized; only certain authorized substances may be used. The authorized substances and uses are identified in Annex VIII, Section B and C of the EC Organic Implementation Regulation 889/2008. For example, the potato starch used to filter organic yeast must not have been produced from genetically modified potatoes.

Whether and to what extent intentional, deliberate or at least negligent behaviour (fault) is required for use in the legal sense is controversial and has not yet been conclusively clarified by the courts.

In practice: it is advisable to take all necessary and reasonable measures, considering the circumstances of the individual case, to detect the presence of GMO-containing or GMO-derived substances in food or feed and the materials necessary for their manufacture (see 4.2). However, if it is found (for example, retrospectively) that a food or feed was unconsciously used as a non-permitted substance, the consequences of the manufactured product, considering the circumstances of the case, must be examined and for the future manufacturing process, including the procurement and control of goods.

The ban on GMOs therefore applies to almost all substances that are used directly for the production and processing of food or animal feed. For all other possible uses (e.g. the use of genetically modified cotton as a packaging material or energy from genetically modified bio-mass) with the exception of veterinary medicinal products, the EC Organic Regulation has a general policy of excluding its use.

- Use of conventional ingredients, additives and processing aids for organic products

Organic food and feed should be produced from organic ingredients or raw materials according to the principles of the EC Organic Regulation. However, the EC Organic Regulation allows the use of conventional ingredients and raw materials if they are not available on the market as organic products (Article 19.2.c of Council Regulation (EC) No 834/2007).
In case of such derogation, conventional ingredients (including additives and flavourings), processing aids, feed additives and processing aids, used in organic, must not contain GMOs and have not been produced from or by GMOs (see 2.3.2).
Additives, processing aids, flavourings, preparations of microorganisms and enzymes, vitamins, amino acids and other micronutrients may only be used if they are specifically authorized for organic production. Authorized substances and uses are identified in Articles 27 to 29 and Annexes VIII and IX of EC Organic Implementation Regulation 889/2008 (so-called positive list). For example, gooseberries and non-organic maize oils may be used to produce organic products. For organic cheeses, conventional starter cultures may be used with microorganisms or enzymes such as the Renin. **Although these conventional ingredients may be used in organic food production, the ban on GMOs still applies to them.**

Conventional products containing GMOs or made from GMOs must be labelled with an appropriate reference (see 2.3.2). They are therefore comparatively easy to recognize.

It is becoming more difficult with conventional ingredients, additives and processing aids, which are often produced by GMOs in conventional food production. In organic food production, such substances may only be used if they have not been produced by GMOs. Since products produced by GMOs do not have to be labelled according to the general labelling regulations, they cannot be identified as such. Thus, it is necessary to obtain a certificate from the supplier that no GMO was used in the process (see 4.2).

Table 2: Summary of the different kind of products involving genetic engineering not allowed in organic

Products	Examples	Status in organic
GMOs	GM rice, GM maize	**Not allowed in organic production** as: - food, - feed, - processing aid, - plant protection product, - fertilizer, - soil conditioned, - seed, - vegetative propagating material, - microorganism - animal
Products produced from GMOs	Oil made from GM soya Flour made from GM maize	
Products produced by GMOs	Vitamin/enzyme produced from Genetically Modified Microorganisms (GMM)	

2.3.3 What is allowed in organic?

In organic production, very small traces of GMOs do not always outweigh the benefits and advantages of organic products and therefore may still be allowed. In addition, the use of veterinary medicinal products involving genetic engineering is permitted. Special exceptions to the GMO ban on use may be allowed by the EU Commission.

- GMO traces

Despite the ban on the use of GMOs, in practice it is not always possible to avoid that organic products contain small traces of GMOs. For example, in the case of seeds for soybeans, complete freedom from GMOs is difficult to be guaranteed.

According to the EC Organic Regulation (Article 9.2 of Council Regulation (EC) No 834/2007 and article 11.2 of Regulation (EU) 2018/848), products with such traces of GMOs may be labelled as organic products unless the general labelling thresholds are exceeded. Therefore, products with a GMO content of up to 0.9% per ingredient or component may be marketed as organic products, if this proportion is accidental or technically unavoidable (see 2.2.3). However, the aim must be to limit the occurrence of GMOs in organic products below the GMO labelling requirement to the lowest possible level.

- Veterinary medicines

A practically important area for which the ban does not apply is veterinary medicinal products. There is no mandatory labelling for medicines made from or produced by GMOs. Such veterinary medicinal products may also be used in organic production.

- Possible exceptions to the GMO ban on use

The Council Regulation (EC) No 834/2007) (Article 22. g) gives the EU Commission the opportunity for the exceptional use of GMO-produced substances. They can be authorized as additives or processing aids if these substances must be used and the substances other than those produced by GMOs are not available on the market. Such exceptions should be kept to a minimum and, if necessary, limited in time.) The Commission can only adopt exemptions in accordance with a specific examination procedure in an implementing regulation (e.g. by amending EC Organic Implementing Regulation).

To date, the Commission has not accepted such exceptions.

In the new organic Regulation (EU) 2018/848), this exception is no longer possible.

Table 2: Summary of the exemption of GMO ban in organic

Exemptions	Examples
GMOs traces	Less than 0.9% per ingredient if unavoidable less
Veterinary products	
Possible exemption to the GMO ban	Regulation 834/2007: if authorized Regulation 2018/889: no exemption possible

2.3.4 GMOs not authorised in the EU and GMOs authorised for specific uses

GMO or GMO-containing or derived GM food or feed not authorized in the EU may not be placed on the market (Article 4.1 Directive (EC) 2001/18). This is called the '0 tolerance' policy. This applies equally to conventional and organic products.

Regarding the kind of products concerned, the '0 tolerance' policy will be implemented differently. For food and seed, there is no threshold: no matter the level of contamination, even the smallest amounts, products contaminating unauthorized GMOs cannot be marketed. Regarding feed, the European Union decided to establish in 2011 (Regulation (EU) 619/2011) a 0.1% threshold: in practice it means that GM feedstuffs should be rejected only if the observed GM content equals at least 0.1% by weight

of the raw material. This only applies to GMOs that are authorized in a third country and for which EU authorization has been applied for, as well as for GMOs whose EU approval has expired.

The GMOs authorized in the EU and the uses covered by the authorization are published on the Internet in the Community Register of Genetically Modified Food and Feed:
http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

There are no labelling obligations for non-authorized GMOs, as they should not be put on the market in the first place. The European Union set up a platform where Member States can notably share food and feed contamination with unauthorised GMOs. Information regarding contamination are made public and available:
https://webgate.ec.europa.eu/rasff-window/portal/?event=SearchForm&cleanSearch=1.

3 Recommendations for farmers

With farmers being the first step of most food and feed production chains, they are potentially the first point of contamination within this chain. A relatively low level of contamination at this stage of i.e. seed, feed, etc. if not checked and eliminated can be rapidly amplified, resulting in a much wider contamination with the associated amplified costs and impact on other businesses. Hence, it is particularly important that famers take specific measures.

3.1 Recommendation regarding inputs involved in organic production

The threat and associated risks to farmers and producer from GM contamination can come from a range of areas such as seed, fertilisers, feed, veterinary medicines etc. Farmers need to be aware of these risks and where the risk lies as well as what to do to avoid or mitigate the risk.

3.1.1 Seeds and other vegetative reproductive material

- Seeds

Seeds are one of the riskiest inputs where GMOs are convened. In order to maintain a GMO-free organic sector, it is essential to be particularly vigilant at this initial stage of production. Species at risk in Europe today are maize, soybean, rapeseed and rice.
To avoid contamination, the safest solution is to only use organic seeds. If conventional, untreated, seed is purchased, GMO varieties must always be avoided. It is necessary to obtain guarantees from the seed supplier on the absence of GMOs in seeds. Where possible, it is preferable to buy seeds that were multiplied in Europe. In case of multiplication outside Europe, it is necessary to require at least one analysis, particularly in case of risky species.
It is recommended to keep samples of seed purchased the previous year and be particularly vigilant about farm-saved seed and keep samples for several years - have analysis undertaken at regular intervals. Analysis can be collective in the case of seed exchange programmes.

- Other vegetative reproductive material

There is currently little risk for vegetative reproductive material as GM versions are not grown in Europe. It is however recommended to take some precautions and only use organic vegetative reproductive material. If conventional, untreated, vegetative reproductive material is purchased, GM varieties must always be avoided. It is necessary to obtain guarantees from the supplier on the absence of GMOs in the vegetative reproduction material.

3.1.2 Products for soil improvement and manure

- Organic fertilizers

GMO risk in organic fertilizers can come either from the incorporation of genetically modified crops or plant material, or from grains or undigested genetically modified fibers in the case of livestock manures/slurries.
In the case of fertilizers, it is necessary to obtain a guarantee of non-incorporation of GM or GMO-derived crops/plants. Farmers should ask the supplier for a guarantee that organic fertilizers do not come from animals that have been fed by GMOs.

- Compost Activators

Where a compost activator or accelerator is to be purchased and used, it is necessary to obtain a guarantee from the supplier that the product is "not derived from GMOs".

3.1.3 Pest and Disease control products

- Micro-organisms and products from micro-organisms (e.g. *Bacillus thuringiensis*)

When biocontrol micro-organisms or products derived from micro-organisms are being purchased and used, it is necessary to obtain a guarantee from the supplier that the product is "not derived from GMOs".

- Vegetable oils from "at risk" species

Vegetable oils from species such as maize, soybean, rapeseed etc., present a risk that they may have been derived from GMO varieties. In the case of purchasing oils from such at risk species either always use organic vegetable oils or obtain a guarantee from the supplier that the product is "not derived from GMOs".

3.1.4 Inputs to animal production

- Livestock

At present, there are no GM animals authorized in the European Union and animals derived from genetically modified species are excluded from organic farming systems.

- Animal feed

Animal feed is currently one of the major GMO risk points for inputs to organic livestock systems, since it generally includes one or more risky raw material (maize, soybean, rapeseed…). While buying organic feed, it is necessary to check possible contamination and the guaranties offered by the supplier:

  - produce only organic feed or not;
  - conditions of transport (if transport is not dedicated to organic, farmers should ask for cleaning certification)…

Test at the reception of the feed lot could be necessary to check contamination.

In the case of maize, soybean, rapeseed, rice and flax, and their co-products (cakes, gluten, etc.) or proteins of potatoes, a number of precautions should be taken. In the case of a complete feed purchase from an animal feed manufacturer, it is necessary to obtain a "non-GMO" guarantee. Farmers should encourage feed manufacturers whose feed lines separate organic and conventional production by placing their order with them. It is also necessary to focus on the guarantees of traceability of the supplier to ensure they are robust enough and find out about the supplier's withdrawal/recall policy.

When manufacturing food on the farm, when possible risky materials should be replaced with less risky materials such as organics materials. It is preferable to use self-produced materials. In the case of self-produced materials, it is necessary to regularly carry out analyses on hazardous materials if GM

varieties of the same species are being grown locally. In case of purchase of organic materials, farmers should obtain a "non-GMO" guarantee from the food supplier and if possible, an analysis result.

Organic feed is necessarily without GMO.
For conventional feed, GMO labelling is mandatory when the product or ingredient has been produced from GMOs above the threshold of 0.9%, contains more than 0.9% of GMOs, contains any quantity of GMO contamination if technically avoidable or is not considered accidental. It is therefore necessary to check labels in feed purchased, but the absence of "GMO" labelling does not therefore guarantee the absence of traces of GMOs in a product used.

It is also necessary to take an interest in your supplier's traceability guarantees.

- Silage Starter Cultures (formic acid, acetic acid, lactic acid, propionic acid)

Where a silage starter culture is to be purchased and used, it is necessary to get a "non-GMO" guarantee.

- Vitamins

Where vitamins are to be purchased and used, it is necessary to obtain a “not derived from GMO” guarantee. A “non-GMO” guarantee is not sufficient, as the vitamin is not genetically modified in itself but is produced from a genetically modified bacterium.

- Yeasts

Where yeasts are to be purchased or used, it is necessary to only use commercially purchased or self-produced organic yeasts and in the case of unavailability, use “not derived from GMO” guaranteed conventional yeasts.

- Fish Hydrolysates and proteolysates

Where fish hydrolysates and proteolysates are purchased and used, obtain a "non-GMO" or “not derived from GMO” guarantee.

- Probiotics

Where probiotics are purchased and used, farmers should obtain a "non-GMO" or “not derived from GMO” guarantee.

- Soy lecithins

Where soy lecithin is being purchased and used, farmers should use lecithin from organic soybeans or from a non-risk material (e.g. sunflower). When using conventional soy lecithin, obtain a "non-GMO" guarantee.

Table 3: Summary of risks and mitigation measures for livestock

Risk	Mitigation
Livestock	At present no GM animals authorized
Animal feed	Check the label
Raw material	Obtain a “non-GMO” guarantee Encourage manufacturers to separate organic and conventional feed lines Focus on suppliers guarantees of traceability Buy organic material Regularly carryout analysis of self-produced material if GM varieties are grown locally
Silage starter Fish Hydrolysates & proteolysates Probiotics Soy lectin	Obtain a “non-GMO” guarantee
Vitamins Yeasts Probiotics	Obtain a “not derived from GMO” guarantee

3.1.5 Veterinary care

The GMOs ban from organics production does not apply to veterinary medicinal products (see 2.3.3). When possible, farmers should try to use vaccines and other medicines not obtained from GMOs or techniques using GMOs, but as labelling is not mandatory, information may be difficult to find.

3.2 How to avoid GMO contamination

3.2.1 General

The cleanliness of organic farms, the adherence to the hygiene programme and the quality assurance on the farm are also able to reduce the risk of GMOs. Indeed, a clean farm attracts less rodents likely to nest and bring plants from outside, including GMO seeds. It is better not to allow dust to accumulate. Farmers should check the content of the contracts that bind them to buyers, especially if they are feed manufacturers.

3.2.2 Production and Harvesting

- Previous Crops

When possible, it is necessary to learn about possible past GMOs from recently acquired plots from the seller and by consulting the plot register of GM crops (if this register exists).

- Avoid contamination by fields adjacent to GMOs

It is also necessary to learn about the presence of nearby GM crops. If there is a nearby GMO field, when possible it could necessary to:

- use early varieties or staggered sowing dates;
- put in place physical barriers (hedges, trap rows etc.);
- sample the 1st rows before harvesting the entire field (for species at risk) and test for GMO presence (strip test).
- voluntarily decommission the 1st rows, or not harvest them, and test for GMO presence (strip test), if economically bearable.

- Remove exogenous plants

There can be a risk from volunteer or other exogenous plants in fields. Particularly with maize or rapeseed in wheat field for example, it is necessary to remove these plants, but also non-maize corn in a cornfield.

3.2.3 Avoid contamination through sowing, harvesting and spreading equipment

To avoid contamination through farming equipment, it is necessary to use equipment that is only ever used on organic farms where possible. If this is not possible, particular attention should be paid to cleaning.

If it is **personal equipment used in non-organic production,** it is necessary to perform a thorough cleaning before any use on organic farms.

If it is **equipment borrowed from a neighbour**, farmers should carry out a complete cleaning before use on organic farms.

If it is **equipment from a farm machinery cooperative**, farmers should check the guarantees of cleaning.

The use of industrial vacuum cleaners effectively cleans combine harvesters between two fields. It could be necessary to request a structured approach, for example by grouping organic farms at the beginning of the campaign.

If the density of organic farms is sufficient in the area, farmers should consider the creation of an organic machinery cooperative or ring, or with sharing of equipment dedicated to organic.

If it is a private company, farmers must require a cleaning certificate.

Farmers should avoid lending small equipment (shovels etc.) to a conventional operator.

3.2.4 Avoid contamination during collection, transportation, and storage

As much as possible, storage and mixed collection of "GM risk" raw materials should be avoided. **Sharing a storage place with a conventional colleague is to be avoided as much as possible**.

In the case of mixed storage (organic and conventional), farmers should check if there is a GMO history and request a complete cleaning of the storage area or request a complete emptying of the entire storage system (in accordance with a risk control procedure).

Farmers should avoid the use of temporary storage systems as much as possible.

"Big bag" type of container previously used conventionally must not be re-used. Particular attention should be given to the cleaning of any material used in common. Before transport to the user or storage agency, farmers should take 3 samples (including one for themselves) before loading, sealed and signed by the carrier. Optionally, farmers should perform a strip test.

After transport from the place of harvest to the place of storage, if the famer is the recipient, he should ask for a certificate of acceptance, with, if possible, results of analyses of the presence / absence of GMOs.

3.2.5 Treatment of the crop

In case of shared drying facilities with conventional colleagues, the 1st organic batch should be sacrificed.
If possible, famers should choose a processor specializing in organic farming. In the case of a mixed type, farmers should then check its guarantees of batch traceability and require a cleaning guarantee before any organic processing and should perform or have regular analyses carried out by the processor.

3.3 When and how carry out analysis?

The risk of GMO contamination is currently low in the EU. However, there is a risk from the limited number of GM crop being grown as well as from feed containing GM material. It is important to know when to test and what test to carry out. See below Table 4: Summary of GMO analysis methods and Figure 1 GMO analysis on farming: How to do it?

Table 4: Summary of GMO analysis methods

Method	Target FMO	Applicability	Fields or Laboratory	Level of detection	Quantitative	Number of seeds to be analyzed	Cost (€)	Deadline for results	Advantages / Disadvantages
Biodosage	Herbicide tolerance	Plantlets	Field	1 grain or 1 seedling	Yes	400 to 2000	30 - 150	6 to 7 days	+ Simple + Cheap + No Laboratory - No Identification - Restricted Application
Strip test	Herbicide tolerance Insect Resistance	plants, seeds, grains, cake, flour	Field	1 grain out of 100 - 800 according to the kits	No	600 - 3000	10 - 40	~ 20 mins	- Detection only + Fast + Cheap + Reliable - Restricted application - No identification if protein common to several GMO
ELISA	Herbicide tolerance Insect Resistance	plants, seeds, grains, cake, flour	Lab	1 grain among 1000	Yes	200 - 400	200 - 350	1 – 2 days	+Detection and quantification + Fast + Reliable - Application restraint -No identification if protein common to several GMO
PCR	Authorised or not authorised	Whole or processed products	Lab	0.1% DNA	Yes	3000	200	1 – 5 days	+ Sensitive +Broad application Identification if transgene - Hard to do - Expensive

Figure 3: GMO Analyses on Farming: How to do it?

4 Food and feed processors

4.1 Where are the risks to the food and feed?

The risks of GMOs in organic food and farming is not confined to just farms as they can also be an equal problem to food and feed processors where their supply chains, and hence their resulting products, can be contaminated by a range of sources in the ingredients that they buy. To avoid contamination, processors must also adopt specific measures.

4.1.1 Genetic engineering in processing and trade

Since the first organic regulation (Regulation (EC) No 1804/1999) and its newer version (Regulation (EC) No. 834/2007, Regulation (EU) 2018/848), the use of genetically modified raw materials, additives and aids in the production of organic foodstuffs and the production of feedstuffs for organic livestock was prohibited by law. At the same time, the development and application of genetic engineering processes for the production of additives and aids have steadily increased, while GMOs cultivation in the EU has always been negligible.

Because of this situation, the organic food industry has been dealing with the GMO problem for several years and is developing strategies to prevent the entry of GMOs into its products. Therefore, the already established measures by organic producers and processors must be further developed and enhanced.

The following parts of the guidelines are intended to assist traders and processors of organic products as well as feedstuffs for organic animal husbandry in the implementation of the ban on gene technology.

GMOs or products produced by or from GMOs can enter the end product in a variety of ways. GMO entry result from:

- Genetically modified ingredients
- Additives in food processing
- Feed materials
- Feed additives

- Risk of contamination from conventional ingredients and processing aids

According to Regulation (EC) No 889/2008 (Annex VIII and XI for food, and Annex V and VI for feed), a limited number of conventional ingredients and processing aids are permitted in the production of organic food and feed for organic livestock farming. The use of such ingredients could be source of contamination, as some of them often involved genetic engineering. Thus, it is important to be aware of what ingredients and processing aids which pose a risk of GMO contamination (see Table 5: Conventional ingredients which may be used according to EC Organic Implementing Regulation Annex IX for organic food and which can be produced from GMOsTable).
All other ingredients in organic food and feeds for organic livestock must come from organic farming in accordance with EU legislation on organic farming and are therefore produced without the use of GMOs.

The following two questions need to be kept in mind:

- Where are the risks associated with GMOs in raw material to be found, in the ingredients and/or in the use of processing aids?
- What ingredients and processing aids pose a GMO risk?

Table 5: Conventional ingredients which may be used according to EC Organic Implementing Regulation Annex IX for organic food and which can be produced from GMOs

Food ingredients (conventional Annex IX)	Made from or by GMOs	Already in use?
Fructose	from transgenic plants	Yes
Rice paper	from transgenic plants	Not clear
Unleavened bread paper	from transgenic plants	Yes
Starch from rice and waxy maize	from transgenic plants	Yes
Fats and oils (with the exception of soya, cocoa, coconut, olives, sunflower, palm, rape, safflower and sesame)	from transgenic plants (e.g. corn oil)	Yes

- Raw material situation

The raw material situation is to be considered more closely in the case of those raw materials produced in both GM and non-GM forms. Firstly, it is important to identify the risk areas, and in particular which GM raw materials are authorized in the EU. The EU keeps a register of authorized GMOs which can be searched at:

https://ec.europa.eu/food/plant/gmo/eu_register_en
http://www.isaaa.org/gmapprovaldatabase/

It should be noted that many genetically modified rapeseed, cotton and maize varieties have only limited food approval. As a result, they may not be marketable, for example, in unprocessed form. Genetically modified rape, maize and soya are widespread on world markets. Soya and maize reach the EU mainly as animal feed. If GMO plants are widely authorized and cultivated in the EU in the next few years, this situation may change fundamentally. Up-to-date information on the authorization of GMO raw materials is available on the Commission website mentioned above.

- Food ingredients and processing aids

The **food industry** uses numerous food components. These components are used as ingredients (including additives) and as processing aids.

- Food additives (ingredients)

GMOs may play a role in the production of additives (see Table 6).

Flavourings are among the allowed additives and are a very diverse group. The Implementing Regulation lays down in Annex VIII natural aromas and aromatic extracts at a flat rate. Flavourings or flavour preparations can be prepared in various ways from or with the aid of GMOs.

Cultures of microorganisms can themselves be GMOs. The cultures may also have been grown on nutrient media prepared from or by GMOs. Trade products of crops may be supplemented with substances produced from or by GMOs.

Some **vitamins, amino acids** and other **nitrogen compounds** can now be produced by means of GMOs. These include, (Vitamin B12, vitamin C (ascorbic acid), vitamin E (tocopherol) or lysine. The following substances, for example: beta-carotene (vitamin AV), vitamin B 2 (lactoflavin, riboflavin).

- Processing aids

Processing aids are a less precisely defined group. In principle, many ingredients such as oils, starches or additives can be used as processing aids. They are required for the production of a product but are no longer technologically active in the end product and generally no longer present. As processing aids approved in accordance with the Implementing Regulation (EC) 889/2008 Annex VIII, citric acid and vegetable oils may be critical in relation to GMO origin.

Cultures of microorganisms and enzymes are approved as processing aids for organic products. Cultures of microorganisms have already been dealt with above. Table 6 below lists important enzymes that are currently being produced and marketed as GMOs.

Table 6: Enzymes which can be produced from or by GMOs

Enzyme name	Intended use
Acetolactate decarboxylase	Beer
Aminopeptidases	Cheese, drinks, spices and meat and milk products, feed additives
Amylase	Starch saccharification, bakery etc., feed additive
Asparaginase	Bakery products
Cellulase	Fruit juice, wine, feed additive
Cyclomaltodextrin	Starch industry
Chymosin	Cheese making
Galactosidase	Diet food, feed additive
Glucanase	Wine, starch industry, feed additive
Glucose isomerase	Starch saccharification, e.g. In lemonades
Glucose oxidase	Baked goods, eggs, mayonnaise
Hemicellulose	Bakery products, starch processing, spirits, feed additive
Hexose oxidase	Baked goods, cheese production
Invertase	Sweeteners
Catalase	Egg products, mayonnaise
Laccase	Beverage production (e.g. coffee, cocoa, tea)
Lactase	Dairy products, ice cream, chocolate products
Lipase	Flavours, baked goods
Lipoxygenase	Bakery products
Mannanase	Feed additive
Pectinase	Fruit juice, vegetables, feed production
Pectin esterase	Fruit juice, vegetables, feed additive
Phytase	Feed additive
Protease	Baked goods, fish, meat, flavours, baby food
Pullulanase	Saccharification
Sulfhydryl oxidase (SOX)	Bakery products
Xylanase	Baked goods, beer, fruit juice

- Feed materials

GM animal feeds are mainly maize and soya. Rape plays a minor role. In the feed sector, a distinction is made between feed materials and feed additives and technical processing aids. Technical processing aids are by definition not ingredients.

In the production of these substances, GMOs may be used in various ways (see 2.3.2) as:

- GMOs
- "products derived from a GMO"
- "products produced by a GMO".

Feed materials

GMOs may also play a role in the production of feed materials. The following table gives an overview of some important substances. Additives can be produced using GMOs. Some additives and processing aids are now considered to be manufactured by GMOs. Cultures of microorganisms can come into contact with GMOs in different ways. Some vitamins and amino acids are produced using GMOs.

The provisions of Implementing Regulation (EC) 889/2008 on the use of conventional feed materials have been applied since the end of 2011. Conventional spices, herbs and molasses can be used in the production of feedstuffs as long as they do not account for more than one per cent of the total annual ration. The Regulation also regulate an exemption for conventional protein feedstuffs up to in pig and poultry feeding, provided that the corresponding protein components are not available in organic quality which is intended to expire at the end of 2017.

Feed additives

Annex VI of the implementing regulation provides for the use of feed additives for organic farming. In the feed sector, this also includes certain substances used as in animal nutrition i.e. vitamins, trace elements etc.

4.2 Measures to take

4.2.1 Obtaining non-GMO ingredients, feed materials and additives

The permitted conventional ingredients and processing aids etc. are laid down in the implementing Regulation's (No 889/2008) Annex VIII and IX and feed materials and feed additives in Annex V and VI for feedstuffs at risk from GMO sources are listed in Table 6. All other components must be procured as organic.

Here the declaration as an organic product - both for domestic goods and for imported goods - is the guarantee that the process-oriented production without genetic engineering, as provided for by the EU legislation for organic farming, has been adhered to.

Most permitted conventional ingredients, additives and processing aids are currently also available as non-GMOs. There are, however, some of these substances where the purchasing of conventional quality was of concern at times. These include in particular:

- Tocopherol
- Vitamin B12, vitamin B2
- Special enzymes

Where there is potential risk, it is essential to check whether these are GMOs or are produced by GMOs.

Information about products that meet the requirements, can be found at:

- www.infoxgen.com/en/
- www.zusatzstoffe.org (German only)
- https://www.soilassociation.org/certification/find-a-licensee/search-for-a-licensee/

For the further development and maintenance of the production of foodstuffs without GMOs, it is of great importance that all food components and processing aids continue to be available in a form that has not been derived from or with GMOs.

- Identity preserved (IP) programmes

Some suppliers of raw materials or products offer the raw materials from so-called IP (Identity Preserved) programs. These programs are designed in a processor-oriented manner. In the few areas of organic food production, where there are interfaces to the conventional market, it is a good idea to access products from such programs. It is necessary to check whether the programs are compatible with the requirements of EU legislation on organic farming. To be on the safe side where there is a threat from GMO and you need to use conventional products, you should choose products from IP programs.

- Where raw materials come from

Special care is needed when purchasing organic raw materials such as maize, soya or rape from countries where GMO versions are also produced or from traders who also trade in GMOs. For these origins and purchasing routes, possible contamination with GMO raw materials must be excluded as far as possible. This can be done through appropriate contracts with producers and/or traders that define the critical points in production, transport and storage to minimize contamination. Furthermore, it is advisable to subject such a product to an analytical check in order to monitor possible mixing effects.

In principle, a declaration of assurances must be requested from the supplier in all "GMO-suspected" ingredients (Table 5) including additives and processing aids (table 6). This also applies to feed materials and feed additives.

Table shows the countries in which GM plants are grown.

Table 7: Worldwide cultivation approvals of GM crops and processed products (as grown in 2016)

Plant	Cultivation approval by country	Examples of processed products
Soya	USA, Canada, Argentina, Chile, Bolivia, Brazil, Mexico, Paraguay, Uruguay, South Africa.	Protein, lecithin, oil; Extraction meal, cake
Maize	USA, Canada, Argentina, Chile, Columbia, South Africa, EU[16] , Philippines, Brazil	Oil, corn protein, flour, starch, sugar
Rape/canola	USA, Canada, Australia, Chile	Oil, meal
Cotton	USA, China, India, Argentina, Australia, South Africa, Colombia, Costa Rica, Mexico, Paraguay, Pakistan, Myanmar, Sudan, Brazil	Oil, protein isolate, methyl cellulose (E 461)
Rice	USA approved, no cultivation; Japan approved, cultivation and import, but not as food; China admitted	Starch
Flax	USA and Canada approved, no cultivation	oil
Sugar beet	USA, Canada	Sugar, syrup, molasses for nutrient media
Potato	USA	industrial use in 2010, very low penetration industrial starch

[16] In the EU, in December 2018, only the GM maize MON810 is authorized for cultivation but 17 countries and four regions have banned cultivation from their territory. Currently, it is only grown in Spain 95,2% and Portugal 4,8%.)

- What are the requirements with regard to stage and chain responsibility, risk analysis and traceability?

The general food and feed law (EC basic regulation 178/2002), which also applies to manufacturers and processors of organic products, results in the following requirements:

- from the so-called stage and chain responsibility of the food business operator,
- the commitment of the food business operator to food safety and the conduct of risk analyses, and
- the traceability of food and feed.

These requirements are partly supplemented by special requirements of the EC Organic Regulations.

Stage and chain responsibility

Stage responsibility means that food and feed business operators at all stages of production, processing and distribution in the activities under their control must ensure that the food or feed meets the requirements of food law applicable to their activity and compliance must review these requirements. Stage responsibility therefore primarily affects your own processing stage.

In addition, each company has a responsibility to ensure that the foodstuffs used in its field of activity meet all the requirements of food law (chain responsibility). Even grocers selling only packaged finished products are to a limited extent responsible for the proper composition and labelling of the products they sell.

Food safety and risk analysis

Food and feed companies are primarily responsible for food and feed safety. They must therefore carry out risk assessment, by means of which critical control points in the production chain can be analysed and controlled (so-called HACCP concept - Hazard Analysis and Critical Control Points -, Art. 6 EC Basic Regulation 178/2002 in conjunction with the EC Regulation 852/2004 on food hygiene, see also chapter HACCP).

Food and feed are considered to be not safe within the meaning of these regulations if they are injurious to health or unsuitable for consumption. In that regard, the same requirements apply to organic production as to conventional companies.

With regard to GMOs, authorized GMOs are considered safe within the scope of the authorization. However, this assumption does not apply to GMOs that are not authorized or not authorized for the respective purpose or use. Food and feed containing unauthorized GMOs must therefore not be marketed (see 2.3.4). In the context of risk assessment to ensure food safety any risks from contamination with unauthorized GMOs must also be considered.

Even though the requirements of the EC Organic Regulation are essentially labelling requirements, organic processing companies must carry out risk assessments with regard to compliance with the organic specifications too.

Organic processors must respect the principles of good manufacturing practice and set up and regularly update appropriate procedures based on a systematic identification of the critical stages in the processing process. These procedures must always ensure that the manufactured products comply with the requirements of organic production. Thus, the implementation of the GMO use prohibition must be part of the internal quality management.

Traceability
General food law contains traceability requirements, which also apply to organic production companies. Accordingly, food and feed business operators must be able to identify every person from whom they produce a food, feed, a food-producing animal or a substance that is intended or expected to be in a food or feed, and to which their products have been delivered. They must set up systems and procedures to provide this information to the competent authorities upon request. Among other things, these requirements serve to enable recall actions when the safety of a food cannot be guaranteed.

- What proof requirements are to be observed?

Anyone who manufactures, or processes organic products must be able to demonstrate within the framework of the requirements for risk assessment and traceability that and how they have ensured compliance with the GMO ban on use. The necessary evidence is set out in Article 9 EC Organic Regulation.

For GMO-containing and GMO-derived substances and products that must be labelled in accordance with the general rules with a reference to GMOs, it is generally sufficient to prove that only those substances and products were used which were not labelled. Processors of organic products may as a rule also rely on compliance by their suppliers with the legal labelling requirements. However, this does not apply if there is information indicating that the labelling of the products does not comply with the labelling requirements. Then the manufacturer/processor must take additional measures that are based on the available information.

If it is known that certain provenances or products are increasingly contaminated with GMOs, the organic producer must increase the effort to avoid GMOs. If, for example, there are general indications that infringements of the labelling obligations occur frequently in certain sectors or sectors, it may be sufficient for the manufacturer/processor to purchase the products only from reliable manufacturers and, if necessary, to additionally certify that the product is not is subject to labelling due to GMOs.

If, on the other hand, the information relates to a specific product, the manufacturer / processor may not use the product until the doubts have been removed. In addition, they must immediately inform their organic control body.

Products other than food and feed (e.g. processing aids) must only be labelled in accordance with the general labelling requirements (see 4.3.2) if they contain GMOs. Products produced by GMOs must under no circumstances be labelled with an indication.

Therefore, if the manufacturer or processor of organic products uses non-organic products, they must ask the suppliers to confirm that these products are not made from or produced by GMOs and it is common control practice to check the existence of these declarations.

4.3 Where are the risks?

4.3.1 Contamination from the farm gate to the end user: problems and measures

More and more GMOs and products made from, or by GMOs, are traded worldwide and used in food and feed processing. Despite extensive separation of the various flows of goods and a comprehensive control system, mixing of organic products with GMOs can hardly be avoided. Frequently, these impurities are in the “parts per thousand range”. Nevertheless, the goal for organic products remains to have as few traces of GMOs as possible. To avoid labelling the GMO contamination in the final product must be at least below the EU threshold of 0.9%.

Section 4.3 identifies where there are risks for mixing with GMOs on the way from the farm gate to the consumer and what measures can be taken in practice. This section also summarizes the most important practice-related results of publications on this topic.

- Transport

Problem: When transporting in open containers (trains, trucks, ships, etc.) there is a great risk of mixing contaminated containers and unintentional mixing.

Activities:
- If possible, transport in closed receptacles such as containers or sacks
- Open containers: thoroughly clean or line the containers with clean plastic tarpaulins
- Use of containers (e.g. company-owned trucks, railway wagons) that transport only non-GMO goods

- Collection points, storage

Problem: Risk of mixing with simultaneous collection and storage of GMO and non-GMO goods.

Activities:
- Transport in closed containers from field to processing and
- Spatial separation of collection and storage sites for GMOs and non-GMO products largely avoids this risk.

- Transfer and loading points

Problem: Each shipment step increases the risk of unintentional mixing due to unclean equipment and conveyor belts, swaps or accidents.

Activities:
- Transport in closed containers from field to processing and
- Spatial separation of reloading points in GMO and non-GMO sites minimizes this problem.

- Processing

Problem: If conventional or GMO and organic goods are processed in parallel at the same time, there are various dangers of mixing:
- Unintentional substitution

- Accidents, operating errors
- Contamination of machines, equipment, conveying systems (e.g. elevators, screws, pipes), containers such as silos, storage cells, bins. For dusty goods, no complete cleaning is possible (e.g. in mills).

Conveyor technology can cause entrainment and left-over product, especially in older plants. For example, material that is not removed by the flushing between batches can accumulate in pipes, elevators or containers. The size of the batch and how intensive the cleaning subsequently required depends on the product being processed and the system its processed in. A "carry-over" experiment undertaken in Switzerland with GMO wheat demonstrated that with normal cleaning and flushing between batches there was still 0.1% GMO content in the flour, 0.5% in semolina and 1.3% in the husk.

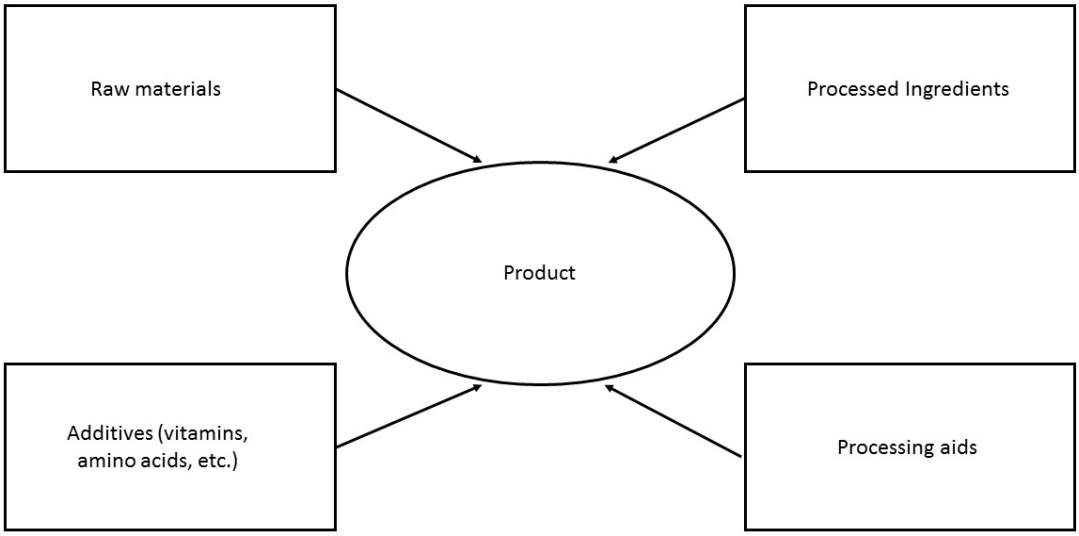
Activities:

- Plant-specific QA system with weak point analysis and measures introduced (sequence of production, cleaning measures, batch overlaps, expulsion quantities, incorrect manipulations)
- Clear flow separation, documentation system; separation of individual batches
- As complete as possible a spatial separation of all steps in the operation such as storage, processing
- If possible, spatial separation of the entire businesses (e.g. Organic mills)
- If spatial separation is not possible, clear temporal separation with sufficient cleaning and separation of batches, depending on the different products and plants
- Establishment of suitable measures for monitoring/analysing contaminations in the context of self-monitoring systems

- Conventional ingredients, additives and processing aids

Problem: Conventional ingredients, additives and processing aids (Annex VIII and IX of EC Organic Implementing Regulation) authorized for the processing of organic products may be GMOs or from GMOs (see Table and Table 6). Both conventional and organic raw materials and ingredients may be contaminated with GMOs. The following table shows possible contamination paths.

Figure 4: Possible pathways with GMOs in food production



1. **Raw materials:** The raw material may be a GMO or contaminated with GMOs.
2. **Processed Ingredients:** The ingredients may have been contaminated with GMOs during the previous processing steps, or they may be GMOs or GMO-derived or GMO-derived products.
3. **Additives (vitamins, amino acids, etc.):** These substances may themselves be products of or from GMOs, or they are grown on carriers or mixed with substances made of or from GMOs.
4. **Processing aids:** The technical adjuvants may be made from or through GMOs or may be mixed with carriers and other substances produced from or through GMOs.

Activities:

- For products (conventional ingredients, additives and other products listed in Annex VIII to Implementing Regulation (EC) No 889/2008) that are used when conventional quality, it is necessary to check whether GMO-critical substances are or can be present in them. Certificates/certificates of origin or manufacturer's declaration should be used to assure that the product was produced without GMOs in accordance with EU legislation on organic farming.
- Many organic associations additionally restrict the use of conventional material in their guidelines; only conventional materials can be used which cannot be replaced by organic ones
- Absolute avoidance of "critical" ingredients that can come from GMOs provides security.
- Information on products that are produced without genetic engineering can be found in the Internet database www.infoxgen.com.

Table 8: Overview of possible regulations on the order of transport, cleaning and disinfection of unprocessed organic vegetable agricultural products and feed

Previous freight Products category	Example of cargoes of respective category	Condition of the loading area	Type of cleaning
1. Very high-risk material ("exclusion list")	Animals, slaughter by-products, skins, meat-and-bone meal Animal manure and soil with animal manure Asbestos, asphalt Metal shot and chips Radioactive materials Sewage sludge, household waste, untreated food residues		Vehicle may not be loaded!
2. Microbiologically contaminated material	Materials with perceptible spoilage (e.g. odour)	No leftovers after unloading	D
	Materials that are infected with salmonella or other pathogens Recyclable waste glass	Remains after unloading	A + D
	Organic waste (organic household waste) Poultry and horse dung	Remains after dry cleaning	B + D
		(Odor) residues after cleaning with water	C + D
3 (O). Materials with physical and / or chemical risk	Fertilizers Garden / potting soil with artificial fertilizer	No leftovers after unloading	B
	Building rubble, recycled waste glass, road salt Metal scrap and turnings (degreased, washed, dried)	(Odour) residues after cleaning with water	C
3 (E). Products with animal protein	Products containing animal meal (exception: dairy products)		C
4 (N). Neutral materials	Food and feed or their raw materials	No leftovers after unloading	A
	Earth / peat Hard coal or brown coal	Remains after unloading	A
	Gravel / pebbles, sand, granite Plastic, (old) paper	Remains after dry cleaning	B
	Chopped green and wood waste	Remains after cleaning with water	C
4 (T1 and T2) Compound feed with nicarbazin, medicated feed with sulphur preparations			A

Legend of Table 8:

Classification of product categories (according to Annex B of the GMP standard for road transport in the animal feed sector, GMP07) O = undesirable substances and products (heavy metals, pesticide residues, mold toxins, etc.) and other (potential) pollutants (physical and / or chemical) E = risk residues of animal protein banned in animal nutrition N = neutral T = additives or veterinary drug risk
Type of cleaning A = Dry cleaning: preferably vacuum B = Cleaning with water: Remove residues of the primary load, rinse with water, high-pressure cleaning, water temperature above 60 ° C, if necessary use brushes C = Cleaning with water and cleaning agents: Remove residues from the primary load, rinse with hot water below 60 ° C, clean with detergent, rinse off D = Disinfection: after cleaning, rinse afterwards.

- Trading

Problem: No guarantee of non-GMO quality due to lack of transparency in flows of goods and missing information; Exchange of goods due to lack of labelling

Activities:

- In practice, it has been shown that guarantees can only be given where a manufacturer can close the whole chain from production to processing and trade. In this case, a positive "no GMO" assurance can be provided via an identity preservation system (IP). These systems are developed by the private sector.

Summary

In summary, three problem areas can be identified, which can be tackled with appropriate packages of measures (see Table 9).

Table 9: Issues and actions in processing aid and trade (modified from[17])

Problems	Activities
Lack of transparency / information in the value chain	• Identity Preserve (IP) • Product-specific vulnerability analysis across the entire chain
Unintentional mixing with insufficient separation of GMO and organic goods	• Strict spatial separation and seamless flow of goods documentation
Substances and products as such, for example GMO feed, GMO enzymes, GMO soy	• Exclusion of critical products, i.e. possibly derived from GMO ingredients and/or use of certain ingredients only guaranteed produced without GM (certificate) • Positive or negative lists

4.3.2 GMO labelling obligations

Processors and distributors of organic products should generally not be met with labelling obligations because of GMOs. As the ban on the use of GMOs means organic products are GM free and the labelling obligation never required. Nevertheless, the knowledge of the GMO labelling obligations is important because the requirements of the EC Organic Regulation refer to them.

- When should food and feed be labelled?

Products consisting of GMOs or containing GMOs and food and feed produced from GMOs must be labelled. Even unpacked food is subject to labelling, as well as food in restaurants and other public catering establishments. The labelling obligation refers to each individual food ingredient or ingredients. For example, the genetic modification must be identified in the list of ingredients behind the ingredient with the "genetically modified" parenthesis.

In the case of food and feed, no labelling is required if only traces are present whose proportion of the respective ingredient or constituent does not exceed 0.9% and the proportion is random or technically unavoidable (see below).

- When do you not have to be labelled?

The labelling requirement does not apply to products produced by GMOs. For this reason, genetically modified food and feed are only those that contain, consist of or are produced from GMOs.

The labelling requirement for GMO-containing, derived and derived food and feed products does not apply if both of the following conditions are met at the same.

[17] Nowack Heimgartner, K., Bickel, R., Pushparajah Lorenzen, R. und Wyss, E. (2002): Sicherung der gentechnikfreien Bioproduktion – Analyse der Kontaminationspfade, bestehende und weitergehende Maßnahmen und Empfehlungen. Schriftenreihe Umwelt Nr. 340. Bern, Bundesamt für Um-welt, Wald und Landschaft (BUWAL).

- Only traces are present whose proportion of the respective ingredient for food or feedstuffs does not exceed 0.9%.
- The contamination is "accidental" or "technically unavoidable".

The question of "randomness" or "technical avoidability" is determined in the production of conventional food and feed according to the type of initial GMO entry. If the accidental or technically unavoidable GMO entry in relation to the individual ingredient remains below 0.9%, no labelling is necessary. This also applies to the subsequent production stages, even if it is known that the starting material has a GMO contamination below the labelling threshold.

As with the processor of conventional products, the processor of organic products is generally entitled to rely on the assumption that its starting materials do not contain GMOs and are not derived from them unless they are labelled accordingly. However, to comply with the GMO ban on use, the processor of organic products must be aware of any incorrect labelling. If they have information indicating a labelling obligation, they may only use the product if they have previously made sure that the material is not actually labelled (see 2.3.3). This is particularly difficult if the threshold of 0.9% is not reached, but the supplier cannot prove that the contamination was accidental or technically unavoidable. In this case, the product must be labelled with a reference to GMOs and must therefore not be used to produce organic products. Traces of up to 0.1% GMO content, if the constructs are authorized as part of foodstuffs in the EU, are generally classified by the authorities as non-labelling relevant.

- When is contamination with GMOs accidental or technically unavoidable?

If food or feed is deliberately produced from a GMO, or if mixtures and contaminants are tolerated from GMOs, the manufacturer cannot rely on falling below the 0.9% threshold. The food and feed must be labelled as GMOs, because the proportion is not accidental or avoidable.

To establish that any GMO-containing or derived material is incidental or technically unavoidable, the food or feed business operator must demonstrate to the competent authority that they have taken appropriate action to prevent the presence of such materials. They are therefore responsible for the obligation to demonstrate and prove to the controlling authority. If the manufacturer cannot prove suitable measures, they must label the product and possibly expect a fine.

Avoidability" in organic food production
Apart from the obligation to provide information on mislabelling (see 4.3.2) regulated by the EC Organic Regulation, there are no stricter requirements for organic products under the EC Organic Regulation than for conventional products.

- Traceability of products containing GMOs and food and feed produced from GMOs

Where organic food and feed manufacturers source conventional ingredients, additives and excipients, they may rely on the label within the scope of the labelling requirements, if there are no indications of a breach of the labelling requirements. It is therefore important for organic food and feed

manufacturers to know what information and documentation obligations their supplier has towards them.

The EC Regulation 1830/2003 (traceability and labelling of GMOs and of food and feed produced from GMOs) has special requirements for traceability. The traceability and labelling of food and feed containing or derived from GMOs must be distinguished between the supply relationships of conventional companies involved in the production of food and feed and the supply of food and feed to the final consumer.
These special traceability rules should make it possible for all parties involved in the manufacturing chain to be informed as to whether a food or feed contains GMOs or whether individual components have been produced from GMOs. For example, traceability rules also apply to foods where detection of transgenic DNA or protein components is no longer possible (as even food made from GMOs, where detection of transgenic DNA is no longer possible, is covered by traceability rules). On the one hand, this should make it possible to provide the right labelling to the end user. On the other hand, the participants in the production chain should be able to reliably recognize that and which GMOs or constituents made from them are contained in a raw material.

- With the transfer of products containing GMOs and food and feed produced from GMOs, within the production change information and information obligations are to be observed by all participants in the production chain except the end consumer (Art. 4 and 5 EC Regulation 1830/2003).
- Supply of food to the final consumer or to providers of catering: there is a labeling requirement (Art. 12 EC Regulation 1829/2003).
- Supply of feed: there is a labelling obligation (Art. 24 EC Regulation 1829/2003).

- What information and documentation obligations exist in the production chain?

The information obligations of the manufacturers differ as to whether:
- A food or feed consisting of GMOs or contains GMOs, e.g. GM soybean, or
- A food or a feed made from GMOs, e.g. soybean oil.

GMO and GMO-containing products
Anyone who for the first time places a product consisting of GMOs or containing GMOs in the production and distribution chain (placing on the market) must notify the buyer in writing;
- That the product contains or consists of GMOs
- Name the specific identifier for the analytical detection of GMOs

The above-mentioned information must be sent in writing to the customer in all subsequent phases of marketing.

Food and feed produced from GMOs
In the case of food or feed produced from GMOs, the supplier must notify the buyer in writing:
- Every single food ingredient made from GMOs

- Every single feed material or additive produced from GMOs.
- In the case of food or feed, without a list of ingredients, confirmation that the product was made from GMOs.

In the case of products consisting of GMOs or containing GMOs as well as food and feed ingredients produced from GMOs, the parties involved (distributors or recipients, i.e. downstream processors) are obliged to establish suitable documentation and information systems or procedures, by means by which the above information can be stored. The obligation to provide information and documentation only applies to the next subsequent processing stage. The parties must store (compulsory) information about the identity of the delivered products and the customer, keep it for five years and make it available to the competent authorities upon request.

- What are the penalties for infringement of the labelling requirements?

Despite the statutory regulation of information obligations, between manufacturers in the food and feed chain for labelling food and feed under the EC Regulation 1830/2003 (traceability and labelling of GMOs and of food and feed produced from GMOs) it is imperative that organic food producers seek a declaration of assurance to safeguard the EC Organic Regulation GMO ban (but also for substances containing or produced from GMOs) and also with regard to warranty and liability issues (See 4.4)

Penalties for intentional violations of the labelling regulations for food or feed will depend on national laws but can be punished with imprisonment or a fine of thousands of euros.

- Who are the competent supervisory authorities?

Who is responsible for monitoring the food and feed law regulations will vary between member states.

- Why should products produced by and with the use of GMOs not be labelled?

The general labelling requirements for food and feed apply only to GMO-containing and derived products. These are distinguished from food and feed produced by GMOs. Food and feed produced using GMOs need not be labelled. The background to this is that, according to the legislature, such products do not contain any material from the genetically modified organism as metabolic products. Accordingly, products produced by and with the aid of GMOs are not subject to the traceability system of EC Regulation 1830/2003.

- When do animal products have to be labelled?

Food and feed of animals such as meat, milk and eggs must be labelled with a reference to GMOs if they are GMOs, contain GMOs or derived from GMOs.

This would be the case, for example, if the animal itself were genetically modified. In that case, the products in question would be at least food produced from GMOs. On the other hand, there is no

obligation to label foods from non-GM animals, even if they receive genetically modified feed, e.g. milk from a cow fed with GM maize.

However, the legal labelling rules do not contain a general exception for foods of animal origin. The distinction between food of animal and vegetable origin comes from the food safety law (food hygiene). There are specific, usually stricter, regulations for food of animal origin because of the particular risks. For example, on the elimination of animal by-products. But, this distinction does not apply in the labelling law.

Conventional animal products (e.g. meat, milk, eggs, butter and cheese) derived from genetically unmodified animals, but which have been fed with GMO feed, do not have to be classified as "GMO" according to EC Regulation 1829/2003.

In organic food production, the use of GMOs feed is prohibited, so this problem does not arise at the level of primary production.

Therefore, honey containing genetically modified pollen falls under the general licensing and labelling requirements for genetically modified food. Even though honey in food hygiene law is classified as food of animal origin. The labelling requirements are also fully applicable to processed products of food of animal origin (e.g. cheese). If cheese contained an ingredient made from GMOs (e.g. genetically modified pepper), the cheese would need to be labelled with an indication of the genetic modification of the ingredient.

- What are the differences between organic products and conventional products in terms of GMOs?

In summary, Table shows the differences between conventional and organic food and feed with regard to the use of GMOs and labelling.

Table 10: Differences between conventional and organic food and feed regarding the use and labelling of GMOs.

Conventional food and feed	Organic food and feed
GMOs and GMO-derived substances may be used, but must be labelled if the proportion per food ingredient or feed ingredient is greater than 0.9% or if that proportion was not accidental or technically preventable.	GMOs and GMO-derived substances may NOT be used if their proportion per food ingredient or feed ingredient is greater than 0.9% or if that proportion is not accidental or technically avoidable.
Substances produced by GMOs (e.g. vitamins, enzymes or lab replacements produced by genetically modified micro-organisms) may be used. Your use does not have to be marked.	GMO-derived substances (eg vitamins, enzymes or lab replacers produced by genetically modified microorganisms) must NOT be used.
GMOs or substances produced from or by GMOs may be used as feed, plant protection products, fertilizers and soil improvers. The products made in this way do not have to be labelled.	To produce raw material from organic production GMOs or substances produced from or by GMOs may NOT be fed and NOT used as crop protection or fertilizers or soil improvers.

- Foods without genetic engineering

The EU compulsory labelling does not require that the marketing of products must be informed of any use of gene technology in the manufacturing process. Due to the special public interest in the non-application of genetic engineering, including outside the organic food industry, voluntary labelling schemes have been adopted at national level.

Unlike compulsory labelling, there are currently no uniform EU-wide regulations. A number of EU Member States have similar but sometimes divergent regulations e.g. "GMO-free" in Austria, "Without genetic engineering" in Germany.

4.4 What to do in case of contamination?

Despite all your precautions, it is possible that you might discover GMO contamination in your crop or products. In this case, it is essential to discover the origin of the contamination in order to be able to eliminate or minimize the risks that it will reoccur in the future.

4.4.1 Actions to be taken by farmer

- **If you discover contamination**

- Notify your certification body.
- Check the content of the contracts that bind you to your buyers.
- Notify buyers who have already received all or part of the lot.
- Notify your organic farming group (if you have one).

- **Contamination discovered in the field**

- Check for total contamination or border contamination.
- Ascertain information about the crops grown by your neighbors.
- Have the preserved seed sample used for seeding the field in question analyzed.
- Check if seedling equipment, etc has been used by a colleague who may have cultivated GMOs and has been properly cleaned (check the cleaning guarantees).
- Depending on the result, determine whether it is a contamination from the neighborhood, from your seed, from regrowth or contamination by manures or slurries or crossed, via the equipment

- **Contamination uncovered in the crop** (farmer)

- Ascertain information about the crops grown by your neighbors.
- Have the preserved seed sample used for seeding the field in question analyzed.
- Check if harvesting equipment, sowing, storage, etc. has been used by a colleague who may have cultivated GMOs, has been properly cleaned (check cleaning guarantees)
- If there has been transport, check the vehicle's cleaning warranties.
- Depending on the result, determine if it is a contamination from the neighborhood, from your seeds, from regrowth or contamination by manures or slurries, crossed, via the equipment.

- **Contamination discovered in a batch including your harvest (contamination found off site)**

- Carry out all the checks in 'Contamination uncovered in the crop" (above) and make sure that the other farmers concerned do the same.
- Make sure that the storage agency does the proper checks.

- **What to do?**

- Depending on the origin of the contamination, refer to the relevant section of this guide and strengthen your warranties.
- If a supplier is involved, ask for stronger guarantees, or change supplier.
- If the contamination exceeds 0.9% and comes from an identified neighboring field, you may be able to claim compensation depending on your national laws.

4.4.2 Actions to be taken by processor

- If you discover contamination

- Notify your certification body.
- Check the content of the contracts that bind you to your buyers.
- Notify buyers who have already received all or part of the lot.

- Notify your organic farming group (if you have one).

- Contamination discovered in a batch (contamination found off site)

- Carry out checks in any remaining raw materials
- Notify suppliers and ask for checks to be made of their martials too
- Make sure that the storage or transport agency the do proper checks.

- What to do?

- Depending on the origin of the contamination, refer to the relevant section of this guide and strengthen your warranties.
- If a supplier is involved, ask for stronger guarantees, or change supplier.
- If the contamination exceeds 0.9% and comes from an identified neighbouring field, you may be able to claim compensation depending on your national laws.

4.4.3 Liability if there is a contractual relationship

Within the food or feed manufacturing chain, there are usually individual contractual relationships between a manufacturer or distributor of raw materials, additives and excipients and other parties involved. These can be for example by an explicit written contract for the supply or processing of raw materials, an oral agreement or the order and delivery of the corresponding goods. If the delivered conventional raw material, additive or excipient contains a genetic contaminant, warranty claims may arise from the contractual relationship with the supplier or contract processor. Possible contractual relationships are:

- A baker gets flour from a supplier that is contaminated with GMOs. Neither the goods batch nor the accompanying documents indicate possible GMO impurities. The baker processes the flour with other non-GMO ingredients. In the case of a food control, it turns out that the flour used has a GMO content of more than 0.9% and the bread is therefore subject to labelling.
- A manufacturer of soy products delivers soybeans to an oil mill so that they can produce soybean oil on a contract basis. In the oil mill GMO impurities of soybean oil go unnoticed. The oil mill delivers this soy oil to the manufacturer.

Within the processing chain, the individual parties are usually connected by a sales contract. In the purchase contract, the ownership of a raw material, additive or excipient would pass to the buyer. However, a contract of employment may also exist between the parties if one company only processes the product for another without wanting to acquire ownership (e.g. in the case of a contract processor). In both cases, warranty rights can be considered as the basis for liability.

- Requirement "defective goods"

In order to avoid these contractual uncertainties in warranty rights, the organic food manufacturer should always require verified confirmation obligatory under the EC Organic Regulation when purchasing conventional ingredients, additives and processing aids from their supplier.

The prerequisite for warranty rights is the defectiveness of the goods. With a 'sales contract' the following cases are to be distinguished:

- The seller and the buyer have agreed in the purchase contract that the goods do not contain GMOs or any ingredients produced from or by GMOs (see 2.3.2). A defect occurs when the seller delivers goods containing GMOs or ingredients made from or by GMOs.
- The seller warrants that the goods do not contain GMOs or constituents produced from or by GMOs (see 4.4).
- Neither seller and buyer have agreed that the raw material, additive or excipient does not contain GMOs or any ingredients manufactured from or by GMOs, nor have they made any provision regarding the intended use of the goods by the buyer. A defect exists if the goods are not suitable for normal use and if they are not in the usual condition of the goods.

In this last case, that no contractual agreement on GMOs or the intended purpose of the goods has been made, the warranty rights of the buyer for goods containing GMOs or constituents made from or through GMOs are not protected. For if there is a defect, in this case it depends on the purpose and the legal requirements for the goods. As a rule, in conventional food production this is usually not seen as a defect, if there is no labelling obligation. By contrast, the use of GMOs is prohibited in organic food production. According to the approach which is relevant for organic production, a deficiency should already exist without special quality agreements if the use for organic production was clearly agreed in the sales contract.

The buyer of a raw material, additive or auxiliary substance whose purchase item is deficient in terms of the GMO ban on use has the following options:

- They may require the processor / dealer to remedy the defect or supply a replacement clean batch or
- They can reduce the purchase price or
- They can withdraw from the contract and reclaim the purchase price or
- They can demand damages

- Different warranty rights

The warranty rights of the buyer of a conventional product are:

- Replacement for the defective purchased item and
- Compensation for damage suffered by the buyer as a result of the delivery of defective goods.

Option 1. Delivery of a defect-free goods lot

The buyer of a defective batch of goods may demand from the seller the removal of the defect (rectification) or the delivery of a non-defective goods (replacement delivery). As a rule, the removal of components which may not be used under the GMO ban on use, will not be possible, so only the replacement of a defect-free batch of goods comes into consideration. As a rule, however, this claim will only make sense as long as the batch of purchased goods is still isolated and not mixed or processed with other raw materials. If it is still isolated and unprocessed, the seller shall bear the resulting

Note : If the buyer cancels the contract, they cannot assert compensation for non-performance of the contract. The cancelation is therefore usually more unfavourable than the claim for damages (see option 4).

expenses, in particular transport, travel, labour and material costs.

It should be noted that the buyer must always offer the seller, the opportunity to deliver defect-free goods and there is a duty, and a right of the seller, to deliver such goods. For this purpose, the buyer

The buyer may require the seller to compensate for the following damages:
• Damage caused by the fact that the seller is unable to deliver a non-defective goods within the agreed deadline
• Damage caused by the delayed delivery of the non-defective goods
· Damage not caused to the purchased item itself, but to other legal assets of the buyer (so-called consequential damage which, for example, result from the further processing of a defective raw material, are also recoverable.

sets the seller a deadline within which the seller should deliver the defect-free goods. The deadline is not necessary if the seller indicates that they are not willing or able to deliver suitable goods. The buyer can only withdraw from the contract or demand a reduction of the purchase price if the seller does not fulfil this obligation within the set period or if the replacement delivery is again defective.

Regardless of the obligation of the seller to deliver defect-free goods, the buyer can in case of damage already occurred e.g. due to mixing, claim damages (see option 4 below).

Option 2. purchase price reduction
The buyer can reduce the purchase price by a statement to the seller. However, as the organic manufacturer cannot use the contaminated batch of goods for further processing, it has no value for them. The reduction due to genetically modified components of the product is therefore generally not relevant and should not be considered further.

Option 3. withdrawal from the contract (purchase price repayment)
Important in the withdrawal from the contract is that the buyer sets the seller a deadline within which the seller should deliver defect-free goods and at the same time indicates that they refused to accept the goods after that date and withdraw from the contract. After expiry of the period, the buyer can reclaim the paid purchase price and hand over the goods to the seller.

Option 4. Damages
A consequential damage to the buyer can result e.g. from the fact that the buyer mixed or processed the purchased goods with other goods free of defects so that they cannot be separated. A food such

as cheese or bread with a GMO ingredient, is no longer able to be sold as an organic product and / or only with a GMO label. In this case the buyer can demand from the seller the reduced value of the whole food, and not just the ingredient, resulting from the impurity.

There is no guaranty by the seller of:
• general advertising statements (quality)
• in the case of mere statements of knowledge and explanations with reservations ("as far as I know")
·the reference to mere descriptions goods, industrial standards, certificates or marks of quality included in the description.

What does the buyer have to prove for a claim for damages?
The buyer of a raw, additional or auxiliary material can enforce a claim for damages in court only if they can prove a defect and the resulting damage.

The seller is not obliged to pay damages if they can prove that they were not responsible for the defect and are not to blame. A distinction is made between intent and negligence according to the degree of blame. The seller deliberately acts (intent) when they, or one of their employees, is aware of the defect when concluding the purchase contract. Negligence occurs when it disregards the care required in communication about the product, i.e. information, documentation or investigation obligations regarding the goods has not been complied with. The seller must prove in the case of any damage that they did not know of the GMO contamination at the time the contract was concluded (intent) and that they did not violate due diligence obligations.

- Guarantee or declaration of assurance and its legal consequences in the case of defective goods

The seller assumes a guarantee if he undertakes in the contract to claim the existence of a specific property of a good as well as all the consequences that would occur in the event of non-existence. With a guarantee, the seller undertakes more than the mere description (quality agreement) of a product as containing no GMOs and no ingredients produced from or by GMOs.

A warranty or assurance statement differs from a quality agreement. In the warranty or assurance statement:
- It does not matter if the seller knew of the defect or not. They are liable when their product objectively and demonstrably has the defect (liability independent of fault).
- The seller is also liable for gross negligence of the buyer, e.g. if the buyer has overlooked the reference to the GMO contamination in accompanying documents.
- The seller cannot rely on a disclaimer because they have provided a warranty or assurance statement.

Whether a guarantee or a mere specification of the quality is needed depends on whether, from the buyer's point of view, the will of the seller to assume responsibility for the absence of the GMO ingredients in a contractually binding manner and thus indicates their willingness to answer for all consequences for any subsequent GMO presence.

In the absence of a clear and effective written guarantee, all circumstances of the individual case must be taken into account. The widespread liability consequences of a guarantee and the lack of, or negligible influence, of the manufacturer of an intermediate product on the raw materials used by them cannot be considered a guarantee. The market place for the respective product and the respective market power of the parties involved can also speak in favor of or against the need for a guarantee.

By confirming to be in accordance with EC Organic Implementing Regulation and its declaration of assurance annexes the seller declares that they are liable for the accuracy of the information (see 4.2). Whether it means only the liability according to the general warranty rules or an additional guarantee may not be clear from the statement itself. Therefore, other written or verbal contractual arrangements are taken into account. For clarity, the statement should therefore be supplemented, or a supplementary contractual agreement made.

For a buyer, a guarantee is always better than a mere statement of quality. However, not every seller will be willing to give such a guarantee. As a rule, a quality agreement is sufficient for the required proof for inspection and / or supervisory authorities that the ban on the use of GMOs has been complied with.

- When are the warranty rights excluded?

The warranty rights (subsequent performance, cancellation or reduction and the claim for damages) may be excluded by a contractual agreement or by legal regulations.

Contractual exclusion
The seller and buyer can contractually agree that the buyer should not have the statutory warranty rights at all or only under restrictions. Of course, such an agreement should be avoided from the buyer's point of view. Since the contractual exclusion can also be included in the general terms and conditions (GTC) of the seller, these are to be specifically considered.

A contractual exclusion does not apply if the seller e.g. has fraudulently concealed the GMO contamination or production from GMOs or has provided a guarantee that the product is not made of GMOs.

The buyer has no warranty rights (legal warranty exclusion):
- If they know the defect at the time of conclusion of the contract, e.g. for example, if the buyer knew that the batch of goods contained GMO impurities, they cannot assert warranty rights. In this case, a suspicion of the buyer is not enough, the buyer must be aware of the actual contamination.
- If the buyer was not aware of the GMO contamination of the batch of goods due to gross negligence at the time of the conclusion of the contract, they can only assert a warranty claim if the seller has fraudulently concealed the contamination or assumed the guarantee for the absence of contamination. The buyer usually not act grossly negligent if they rely on information provided by the seller regarding freedom from GMOs and does not examine the batch of goods. However, the legal situation is different for merchants (see below).
- If the purchase is a commercial transaction for seller and buyer and the buyer has not complied with his inspection and complaint, they cannot assert a warranty.

Inspection and complaint obligations in the trading business

The duty to inspect and to complain is explained in more detail on the basis of its importance.

Trades are all transactions of a merchant that belong to their business. If the purchase of goods for both contracting parties is a commercial transaction, the buyer must inspect the goods immediately after delivery, insofar as this is reasonable, in accordance with the orderly course of business and, if a defect is found, inform the seller immediately. What is reasonable is objectively determined taking into account industry, company size, costs, technical and organizational effort, previous defectiveness and likelihood of error. The amount of any consequential damages (for processing defective products)

For commercial transactions:
• Normally, the declaration of the goods must be checked, i.e. there must be no evidence of a genetic change, e.g. on label or accompanying documents of the goods
• Regular sampling should be undertaken, taking into account the above criteria, such as the size of the enterprise and the likelihood of contamination.
· If there are indications of contamination, the condition of the goods must be examined more closely. It is advisable to regularly take samples of the goods and undertake a laboratory analysis, which clarifies whether the goods contain traces of GMO contrary to the declaration.

will be relevant to the perception of the industry, specific business and commercial practice.

For example, it depends on these criteria whether, and to what extent, laboratory analyses of samples are required. Also, some properties, such as the production from or by GMOs, cannot be proven analytically. Instead, the buyer may require the seller to submit other appropriate supporting

A manufacturer/dealer may, under certain conditions, claim damages from a supplier/processor for damages caused, for example, caused by GMO conventional ingredients or by GMO contamination of other organic ingredients of the injured party even if:
• there is no contractual relationship between the damaged manufacturer / dealer and the damaged supplier / processor
• the contractual claims are already time-barred
· the buyer does not complain about defective goods in a commercial transaction.

documents, such as i.e. explanations of his pre-supplier.

The type and frequency of incoming inspection should be part of the quality assurance program for medium to large enterprises (see 4.2).

Sampling must be undertaken in a suitable way in such that it meets the requirements to ensure the representativeness of the goods.

- Liability, if there is no contractual relationship

Even if there are no contractual relationships between participants in the production chain, the injured manufacturer or dealer may, under certain conditions, claim damages from a supplier or processor in the production chain.

What are the conditions for liability?
The manufacturer of a raw material, additive or auxiliary substance must have caused an infringement of property by an unlawful and culpable behaviour at a manufacturer or dealer.

Property infringement
Ownership of a multi-ingredient foodstuff may be infringed by the total food being lost as an organic product as a result of GMO contamination of a supplied ingredient. For example, if the injured party blends or processes a GMO-derived raw material, adjuvant and excipient with other organic ingredients, thereby preventing the product from being labelled as an organically produced product. It does not matter if the ingredients are just mixed (e.g. the flour mix for a bread) and cannot be separated or if they have already been processed into a food (e.g. the baked bread).

Violation of a duty of care obligation
In addition, the manufacturer of a product must have acted contrary to the law. This can be done by violating their duty of care. The manufacturer's duties of care include, among others, the avoidance of manufacturing, instruction and product observation errors. The duty of instruction also applies to every trader of raw materials, additives and processing aids.

When placing on the market a product containing GMOs or produced from GMOs, the manufacturer is required to inform the buyer in writing of each of the food and feed ingredients produced from GMOs (see 4.3.2).

Fault of the manufacturer
The manufacturer must have been also culpable. This is the case, if they have caused a property infringement intentionally or due to negligence, such as by a GMO contamination. The producer is intentional, if they knew that the GMO product contains or was produced from GMOs. Negligence occurs when they disregard the care required in communication. The due diligence obligations include

In order to order to receive damages, the injured party must prove that:
• Property infringement has occurred to their products.
· the property infringement is based on genetically modified raw materials or additives and excipients originating from a particular manufacturer and already genetically modified on delivery.

the labelling and traceability requirements (see above) and obligations to avoid manufacturing defects.

Damage of the manufacturer
The property infringement must have caused damage to the property of a manufacturer. This is the case if the manufacturer can obtain a higher sales price for the product without the GMO impurity than with the GMO impurity (mercantile inferior value).

- What proof obligations does the injured manufacturer or dealer have?

Compensation can be enforced in court only if the damage and its causation can be proved. If the injuring party denies culpability and the injured party fails to prove it, the court must dismiss the claim. It is therefore advisable to retain evidence from all purchased batches.

If the production of organic food involves the mixing or processing of several ingredients with GMO impurities and it is not possible to determine clearly which ingredient caused the impurity in the end product, all potential culprits are jointly and severally liable. Potential infringers are those suppliers whose raw material or ingredient lot contained GMO impurities. The injured party may claim compensation in full from any of the suppliers concerned. This assists the injured party because they do not have to prove the damage share of the individual suppliers.

- Does the injured person get the costs for damage monitoring replaced?

Irrespective of whether or not there is a contractual relationship between the parties involved in the production of food, the following applies.

Cost of damage monitoring in case of damage
If it has been proven that GMO contamination has occurred, the costs of the analysis and the samples required to secure the evidence are also reimbursed.

Cost of preventive damage monitoring
If the analysis of the raw materials or end products reveals that no contamination has occurred, the trial and analysis costs are generally not reimbursed. Civil liability presupposes an economic damage that has already arisen or is imminent. However, sample and analysis are usually merely preventive in nature.

- Insurance cover for GMO damage?

For the buyer of goods, but also as a supplier, the question arises whether operating and product liability insurance covers damage to goods e.g. made or using genetic engineering.

Manufacturers and dealers usually have company and product liability insurance policies, which refer to the "General Conditions of Insurance for Liability Insurance (AHB)" and special insurance conditions for this type of insurance cover. They are thus part of the insurance contract. What is and isn’t covered or available will vary between member states. For an example in Germany, as a rule, these insurance conditions are based on sample conditions of the German Insurance Association (GDV).

Until 2004, there was no GMO exclusion in the AHBs. Since 2004, however, GDV has included in its model AHB 2004 a genetic engineering exclusion recorded (as of October 2010). Thereafter, the insurance excludes:

"Liability claims for damages caused by:
- genetic engineering work
- genetically modified organisms (GMOs)
- products containing or derived from GMOs or produced using GMOs "

The GDV model conditions for the recall cost liability insurance for manufacturers and trading companies (as of August 2008) contains a corresponding exclusion for claims arising from recalls due to GMOs.

The model conditions and thus also the exclusion of genetic engineering are recommendations of the GDV. The individual insurances can sometimes deviate significantly from the recommendations. In

general, however, the general insurance conditions of the insurance company will also contain corresponding exclusion clauses.

Since the insurers only use the new AHB for new contracts and contract amendments, it can be assumed that damage to GMOs is not yet ruled out in the unmodified old contracts (before 2004). It should be noted that the insurer must formulate a GMO exclusion explicitly in the contract, if they do not want to insure such risks.

5 Conclusion

In order to preserve consumers and clients trust and to be compliant with the philosophy of organic agriculture, it is crucial to avoid GMOs contamination all along the food chain productions. Measures must be taken by the Organic Sector but the European and national legal framework must enable organic production to remain GMO-free.

The Organic Sector has worked on developing strategies to remain GMO-free. In that regard, the development of organic breeding[18] is particularly important because transparency on breeding methods is not yet mandatory and because seeds are the first steps of production.

But measures to avoid contamination are particularly costly, when not impossible[19]. It is therefore crucial for the organic production to have an efficient legal and agricultural context.

That is why IFOAM EU, through its project 'Keeping GMOs out of organic'[20] will continue its advocacy work at many different levels [21]:

- No new approvals of GMOs for cultivation at the European level.
- Upholding of national ban on GMOs cultivation.
- No introduction of contamination thresholds in seeds.
- Adoption of strict and efficient coexistence rules at national levels when GMO cultivation are authorised.
- Implementation of the polluter pays principle.
- Make sure that GMO-free alternative will continue to be available (like GMO-free vitamins…).

In the coming months and years, the advocacy work regarding new genetic engineering techniques will be particularly important. IFOAM EU demand the full regulation of all new techniques under the GMOs regulation as well as the impossibility to market any GMOs or 'new GMOs' without detection methods available. Those are the essential conditions for the Organic Sector to remain compliant to the organic standards. To enable liberty of choice of farmers, processors and consumers, it is also necessary to give full transparency of the breeding methods used on marketed seeds.

The unprecedented development of organic agriculture[22] in the European Union is a clear message from citizens: they want more transparency on food production and a more sustainable agriculture, without GMOs nor chemicals. European and national stakeholders must make this possible.

[18] See LIVESEED project.
[19] IFOAM EU, Socio-economic impacts of GMOs on European agriculture, 2017.
[20] More information on the project on IFOAM EU's website.
[21] IFOAM EU, Preventing GMOs contamination: an overview of national 'coexistence' measures in the EU, 2014.
[22] https://www.ifoam-eu.org/en/organic-europe.