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# Food Product Imports from Third Countries into the European Union

## A Guide

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**BÖL**

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## 1 Introduction

The market for organic products has continued to expand, with double-digit growth.

More and more organic products marketed in Germany come from neighboring European Union countries and from other nations outside of the Union, the so-called “third countries”. Third country imports are no longer the “traditionally” imported agricultural products, that is to say, those that cannot be grown in Europe, such as coffee or tea. Nowadays a good part of the classical dried organic products come from China, organic cereals are imported from Ukraine and organic early potatoes cultivated in Egypt are offered in markets and health food stores before locally-grown ones are available.

Whereas within the European Union the Regulation (EEC) No. 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (Council Regulation on Organic Agriculture) are mandatory in all of the Member States and are the legal framework for producers, processors, and traders, in third countries deviations from the regulation’s provisions are frequently occurring.

That is due to the fact that the conditions for the production and processing of organic food in third countries are often quite different from those in the member states of the European Union. Often third country organic crop farmers have minimum knowledge of organic standards. Seldom is there a technical assistance structure actually in place and working. Often these farmers are under the misconception that organic farming simply consists of abstaining from using prohibited synthetic mineral fertilizers and pesticides on the crops. The conversion to organic farming is mainly motivated by a desire to export. There are no state incentives for organic farming so there is no risk of having to pay back the subsidies if regulations and requisites are not met.

It is not customary for farms in third countries to convert all of their fields to organic production. Livestock are often raised solely for the owner’s consumption and the activity of livestock raising is almost always conventional. Often the export crops are organically cultivated whereas the field crops aimed at local markets or for the owner’s consumption are conventionally cultivated. Fertilizers, phytosanitary products, ingredients and processing aids not contemplated under Council Regulation on Organic Agriculture are used. Especially for developing countries, the demanding requirements of documenting production methods, procurement and use of farming inputs as well as the sale of organic products are difficult for small farmers to implement. The inspection bodies that operate in third countries apply the concept of group certification for smallholders, which is not included in the EEC Regulation. Surprise inspections are made notably less frequently than in EU countries.

That occurs because the Council Regulation on Organic Agriculture does not demand a 1:1 application of the regulations; it also permits equivalent production regulations and control measures (Chapter 2).

Consumers, however, trust the organic seal, whether or not the product is from within the EEC or imported from a third country. This guide is intended to be an aid to guarantee the organic quality of the products imported from third countries. It indicates important risk areas and possible deviations and also indicates the measures needed to avoid unacceptable deviations.

Thus, it provides third country exporters with orientation for the generation of their organic products and for their respective organic projects, and importers with the most important information for evaluating the equivalence of the organic products to be imported. This is particularly relevant to EU importers.

## **2 Legislative Framework**

In December 2005 the European Commission issued a draft for the complete revision of “*Regulation (EEC) No. 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs*”, in force since 1991. European Commission representatives championed the need for a complete reform, using the following arguments:

- (1) The Council Regulation on Organic Agriculture currently in force would be obsolete in terms of legal systems, and the system issued in June 2004, “European Action Plan for Organic Food and Farming”, would contemplate a reform;
- (2) The European Court of Auditors objected to supervision and follow-up controls being done at the EU level, in a special report issued in March 2005, and
- (3) The regulation on third countries in Regulation (EEC) No. 2092/91 is not compatible with World Trade Organization (WTO) rights, based on the results of a claim (“WTO-Panel”) filed by the United States and Australia against the EU Regulation on the Protection of Geographical Indications.

The European Commission especially insisted that a high priority would be the modification of the third country regulation. The intention was for the third country regulation to be integrated into Regulation (EEC) No. 2092/91 in force before any modification of the latter was made. After intense negotiations, in December 2006 the EU Council of Ministers approved a Commission proposal to reformulate the legal provisions for third countries pursuant to Regulation (EEC) No. 2092/91 Article 11. These provisions entered into force on January 1, 2007, after the supplementary Regulation (EC) No.1991/2006 was published which modified Article 11 of Regulation (EEC) No. 2092/91.

Given that on January 1, 2009, Regulation (EEC) No. 2092/91 will be substituted by the new EU regulation on organic production and indications, Reg. (EC No. 834/2007, it became necessary to integrate the new third country provisions to this new regulation. That is provided for in Section VI Articles 27 and 27a of said regulation.

When an import company residing in the EU wishes to import organic products from third countries into the EU, there are three possible manners of doing so:

- (1) The third country applies Council Regulation on Organic Agriculture exactly as the EU member states do (“**Compliant Products**”). In cooperation with the EU member states, the European Commission recognizes the inspection bodies authorized to inspect and to certify in third countries.
- (2) The third country applies production regulations and control measures that are equivalent to Council Regulation on Organic Agriculture (“**Equivalent Products**”). In this case EU recognition may be obtained as follows: the third country in question is incorporated into a list of third countries recognized as equivalent (“List of Third Countries”) that is maintained by the Commission. Another method would be for the inspection body operating in the third country to have been incorporated into a list of “equivalent” inspection bodies by the European Commission in agreement with the EU member states.
- (3) Until the first list of “equivalent” inspection bodies is issued, there is a transitory solution, a third alternative to be chosen: an import authorization, pursuant to Regulation (EEC) 2092/91 Article 11 (6). When an operation in the third country implements production regulations and control measures that are equivalent to Council Regulation on Organic Agriculture and the competent EU authority has granted the EU importer an import authorization, it is also possible to import organic merchandise from third countries. Such import authorizations may be granted by the EU member states until 12 months after the Commission has issued the first list of inspection bodies recognized as “equivalent”. They may be valid until a maximum of 24 months after the Commission issued the List of Third Countries inspection bodies.

At the moment this publication was finalized, the Commission lists of “compliant” or “equivalent” inspection bodies had not yet been issued. Therefore, currently imports from third countries into the EU may be done using the List of third countries and the import authorizations.

#### *List of Third Countries*

Until now only seven third countries have been recognized by the EU as countries with equivalent organic farming standards and included in the list of third countries, Regulation (EEC) No. 94/92. They are Argentina, Australia, Costa Rica, India, Israel, New Zealand, and Switzerland.

For each one of those countries, the annex of Regulation (EEC) No. 94/92 names the product categories, the origin, the inspection bodies recognized by the EU and the institutions that can grant certificates of inspection pursuant to Regulation (EC) No. 1788/2001. For example, from Costa Rica only organic crop products can be freely imported into the EU. They must be produced in Costa Rica itself. Only two inspection bodies have been approved for exports to

the EU. Pursuant to Regulation (EC) No. 1788/2001 certificates of inspection are granted by the Ministry of Agriculture in San José.

The existence of legislation governing organic farming is a requisite for a third country to be included in the list of third countries. Therefore, it is necessary for the third country's respective ministries to set forth legal requirements for agricultural production, processing, and the inspection system. Only after the approval and introduction of such regulations, may the third country file a request to be included in the list of third countries with the European Commission, through its diplomatic representation office in Brussels.

After the request is received, the European Commission Food and Veterinary Office (FVO) makes an inspection. Its headquarters is located in Dublin, Ireland. That Directorate conducts inspections in the EU Member States and in third countries, for the purpose of verifying that European legal provisions are adopted and implemented.

First the FVO sends the FVO comparison tables to the competent authority in the requesting third country. In these tables, the legal regulations of the third country are entered and compared to the provisions set forth in the Council Regulation on Organic Agriculture and are then evaluated for equivalence. Afterwards an inspection visit is made by FVO and selected EU Member State representatives.

The inspection reports are published on the FVO Web page ([http://europa.eu.int/comm/food/fs/inspections/fnaoi/reports/organic\\_farming/index\\_en.html](http://europa.eu.int/comm/food/fs/inspections/fnaoi/reports/organic_farming/index_en.html)). After the non-conformities observed during the inspection visit have been resolved, the European Commission and the EU Member States decide whether to incorporate the third country into the list or not. After the country is included, the FVO makes periodical visits.

After a country is incorporated into the list of third countries, it is possible to freely import certified organic products from that country into the EU Member States. Nevertheless, a certificate of inspection must be obtained for every importation lot, pursuant to Regulation (EC) No. 1788/2001.

#### *Import authorization*

Under this option, the European Union importer must prove to the corresponding European authority that the third country production regulations are equivalent to those set forth in the Council Regulation on Organic Agriculture. In addition, the EU importer must document that the inspection measures in the corresponding third country are "equally efficacious" as those indicated in Council Regulation on Organic Agriculture and that they are carried out constantly and effectively.

Once an inspection body in the third country confirms through inspection and certifies that the agricultural production, processing, and exportation of the products corresponds to EEC organic farming requirements, an importer in the European Union may request an import authorization from the corresponding competent authority.

The request must document the equivalence of the production and of the inspection measures and must justify any deviations in the third country from the provisions in the Council Regulation on Organic Agriculture. The inspection body that operates in the third country must corroborate the information in the request as well as the continuous and effective implementation of the inspection measures in the third country. Besides the request, the EU competent authorities normally request additional documentation. For example, they request certificates and copies of the reports of the on-site inspections made in agricultural companies or cooperatives, in processing companies, and in the export company.

The inspection body that operates in the third country must comply with the requirements in European standard EN 45011 or in ISO Guide 65. These are internationally recognized standards that describe the manner in which agencies that operate product certification systems must do their work. The EU competent authority also often asks the inspection bodies for the corresponding evidence.

The import authorizations are generally valid for one year. During that term, the importer in the EU may import organic products from the exporter indicated in its request for up to the maximum volume indicated therein. That is to say, it is not necessary for the importer to file a request each time that it wishes to import a new lot, provided that it does so using the same exporter, the same processing companies, and the same agricultural suppliers. If there are modifications, a new request must be filed.

After having been granted the import authorization, each lot of goods to be imported into the EU must be accompanied by a certificate of inspection pursuant to Regulation (EC) No. 1788/2001.

### **3 Deviations from Regulation (EEC) No. 2092/91 in Third Countries and Measures to Guarantee Equivalence to this Regulation**

#### **3.1 Agricultural Production**

##### *Conventional Production Units*

In principle, converting the entire farm to organic production is the most recommended option. Managing a conventional production unit and an organic production unit in parallel considerably increases the risk that, if certain difficulties arise, inputs prohibited in organic farming may be resorted to, given that they are readily at hand.

For cases involving parallel production, Regulation (EEC) No. 2092/91 sets forth the incorporation of the conventional unit(s) into the inspection system. To do so, first of all in the unit description the parcels and storage areas that correspond to one production unit or another must be clearly differentiated (one manner to do so would be identifying them in the corresponding blueprints). Then, all of the measures that enable reliably delimiting the organic production units from the conventional ones must be implemented. It is important to properly train the workers in such matters.



In addition, management measures must be documented in such a manner that the use of the different agricultural inputs (seeds, fertilizers, pesticides) and the records of the various harvests and products for sale for the organic production unit and the conventional one alike are transparent, understandable, and verifiable. For such documentation, records indicating the quantity and dates of any inputs used, the harvested volumes as well as a storage log and marketing records should be used. It is important for separate records to be kept for the organic unit and for the conventional unit. The governing principle here is that the company can at any time prove without any possible doubt that it is operating in equivalence to the provisions set forth Regulation (EEC) No. 2092/91, by showing its working method and its records.

The conventional production unit must also be inspected during the inspection body's visit. The inspection report must also deliver conclusive information on the conventional production unit inspection results.

#### Practical Example

In many Latin American banana-producing regions, organic production and conventional production are managed in parallel by the same producer. In such a case, a clear differentiation of the two production units is of vital importance to avoid "a miraculous multiplication of organic bananas" or conventional treatment of organic bananas.

The description of each production unit must clarify how bananas' need for nitrogen and potassium is met, and how diseases such as Sigatoka are dealt with. Material safety data sheets must be submitted for the fertilizers used (generally commercial products).

The workers must be constantly trained in organic production guidelines and the documentation of such training must be kept for inspection purposes.

The use of distinct agricultural inputs must be documented in daily work logs and field-plot card-indexes. The coherence of the recorded data is verified during the announced and unannounced inspection visits. For example, as the same machinery and devices (fumigation pumps, aerial spraying planes) are used to implement phytosanitary measures for the organic production unit and for the conventional production unit, the effective cleanliness of such implements must be guaranteed before using them in the organic production unit and such cleanliness measures must be recorded. The inspection must pay special attention to that risk area. For banana crops, inspection also includes the aerial spraying companies subcontracted for the fumigation. Another source of information regarding the use of prohibited inputs is a periodical analysis of the foliage.

#### *Parallel Production*

For annual crops, Regulation (EEC) No. 2092/91 prohibits parallel production of the same variety or of varieties that cannot be easily distinguished. That must also be taken into consideration for crop planning in third countries, to decrease the risk of mixing or

interchanging organic products with conventional products from the same harvest. Rotating crops during different periods of the varieties in question may be useful.

For perennial crop parallel production, Regulation (EEC) No. 2092/91 sets forth that it is solely permitted for a limited period of time specified in the context of a conversion plan. In the event that a company cultivates both conventional and organic perennial crops in parallel, appropriate measures to guarantee that the respective productions are kept separate, without any mixing or interchange, must be taken. That may be done by clearly identifying the harvest products in question and having impeccable documentation of the harvest and warehousing. For example, measures to facilitate the above are to harvest the conventional products on different days than the organic ones and store them in differently-colored containers. It is essential to keep workers continuously informed of the difference between organic products and conventional products and to teach them the importance of handling them separately.

Regulation (EEC) No. 2092/91 also stipulates obligations to notify the inspection body when harvesting is to be carried out as well as the quantities to be harvested, in order to reduce the risk of mixing or interchanging organic products and conventional ones.

#### Practical Example

In North Africa the harvest of organic oranges is done on determined days. The dates are communicated to the inspection body for it to verify compliance by taking a random sample.

In the packaging center, the packing line is meticulously cleaned before packing the organic oranges; such cleaning must be documented. In addition, it is necessary to document that the oranges have not been treated with any prohibited substance (for example, disinfectants in the water or thiabendazole in the waxing). Those risk areas must be carefully evaluated during inspection as well, for possible contamination (for example, through the fungicides on the fruit waxing brushes).

Pursuant to Regulation (EEC) No. 2092/91, when one farm has both organic and conventional units, it is prohibited to have the same livestock species in both units (the sole exception would be for research purposes); besides, this is not a common practice in third countries.

Rather it is customary for a company devoted to organic agricultural production to raise its livestock in the conventional manner, feeding it conventional fodder, in parallel, without the livestock being subject to the inspection system. So it is necessary to evaluate if the animal manure from conventional livestock raising may be used. (Is there a need for it? Does the manure come from an extensive production?) In principle, composting/fermenting animal manure is recommended. It is also necessary to analyze potential risks, for example, when mixing poultry manure from intensive husbandry or when incorporating synthetic NPK fertilizers to improve the compost.

*Reduction or Retroactive Recognition of the Conversion Period*

Often third country farmers interested in converting their conventional production unit to organic production tell the inspector on his/her first visit that they have not applied any prohibited fertilizer or phytosanitary product on their land in a long time. That may be true but it is hard to prove. However, frequently a reduction in the conversion period is considered. By doing so, often the fact that the area may have considerable erosion problems, and therefore is not yet suitable for organic farming, is not taken into account and, in the end, the unit is not apt to be certified for organic production.

Many times retroactive recognition confers an important economic advantage because the products may be merchandised sooner as organic products. Therefore, the inspection bodies in the third countries involved in the process as well as the competent authorities who grant the import authorizations place great importance on documentation verification, to have grounds for retroactive recognition depending on the former use of the land.

If a company is striving for retroactive recognition, it must carefully prepare its documentation, in order to convince the inspection bodies involved and the corresponding competent authorities. For probatory documentation, the operation may submit photographs and films over various years that clearly show the state of the fallow fields in the areas in question, evaluations and certifications from scientists or authorities in the field of study, which prove the non-use of unauthorized inputs, as well as inspections of the fallow fields made by the inspection bodies before the field is converted into farmland.

#### Practical Example

In the Balkans a company wants to convert fallow fields into farmland for cultivating herbs. Considering that an inspection was not possible before the land was tilled, the project manager in coordination with the inspection body took photographs that clearly show the land as fallow fields over several years. As this was a company with long-time experience in organic production, that evidence was considered sufficient.

It is important that the areas for which retroactive recognition is being requested meet organic production guidelines. Organic production principles do not contemplate converting natural or fallow fields into farmlands if they are at high risk of erosion and are not apt for agricultural production due to their location, even if no unauthorized fertilizers or phytosanitary products whatsoever have been applied for the past three years. Nor is the conversion of natural areas that are specially protected due to environmental fragility acceptable. When requesting retroactive recognition of the conversion period, a sound concept based on principles of organic agriculture must be submitted regarding how to maintain or improve soil fertility. For example, that would include a crop rotation program, cultivation of legumes and green manure, intercropping, the use of animal manure and other organic materials for erosion control (anti-erosion trenches, quickset hedges or permanent cover crops). During the first inspection visit, farmers can usually only indicate that they intend to implement organic production methods in an exemplary manner, and how they intend to do so. So, generally, the

actual implementation of organic production methods can only be reliably verified during the second inspection. For example, erosion furrows may often only be observed some time after the fallow fields have been tilled. Also only after a considerable time can it be determined if the organic production unit has implemented erosion control measures. Thus, a conversion period of a minimum of one year would be recommended for all requests even when it has been completely proven that no prohibited substances have been applied in the areas in question. That is the only manner to guarantee organic production, not merely the non-use of unauthorized inputs.

#### *Deviating Inputs*

Fertilizers, phytosanitary products, and feedingstuffs that are not included in the positive lists in Regulation (EEC) No. 2092/91 Annex II may be considered deviating inputs.

Given that Regulation (EEC) No. 2092/91 was solely created for the EU Member States, several of the inputs used in non-European regions are not found on the positive lists in Annex II. It is possible to allow the use of such inputs because Regulation (EEC) No. 2092/91 stipulates equivalence, not total compliance, with the production standards in the regulation for third country product imports. When granting an import authorization, for the corresponding inspection body and competent authority to be able to recognize and assess the application of an input not included in Annex II as an equivalent, specific information is required, depending on the input. For extracts of local plants used as a phytosanitary product, their composition, their performance, and toxicity when applied must be known; clarification may also be needed as to whether the extract is used more as a strengthener than in its function as a phytosanitary product. For fertilizers, specifications on their composition and the solubility of their nutrients must be submitted. At any rate, the use of local inputs not included in Regulation (EEC) No. 2092/91 must first be agreed upon with the inspection body.

#### Practical Example

In an agreement reached between the inspection body and the competent EU authority, the use of chili powder to control certain pests in horticulture was approved. The decisive elements for the approval of the competent authority and of the inspection body were statements by scientists and local authorities regarding harmful nature, toxicity when applied, environmental effects and residues, in addition to the fact that chili powder is traditionally applied in the local agriculture.

#### *Wild Crop Collection*

Regulation (EEC) No. 2092/91 sets forth the following demands for the organic certification of wild collection:

1. Non-application of prohibited substances during the past three years and

2. No damage to the natural habitat and to the ability of the species that is being collected to survive in the area in which it currently grows wild.

Some of the competent authorities within the EU Members States demand certificates from local authorities when said conditions are met. In many cases, it is impossible to obtain this type of certificate because the third country authorities do not feel that they have sufficient expertise to issue them. What's more, this type of certificate only makes sense if the local authorities have the expertise needed to be able to issue a certificate that can be trusted. That may occur, for example, in traditional wild collection regions where the State monitors the wild collection to avoid excessive collection. If it is not possible to obtain this type of certificate, the compliance with the wild collection criteria must be proven in some other manner. Besides the on-site inspection conducted by the inspection body, the collection area must be carefully selected, and all of the activities conducted on it and other pertinent information must be carefully documented, in language that is easily comprehended, in order to minimize the risk of including some unauthorized species in the collection. To ensure that the natural habitat and the species being collected are not affected, various evidence may be considered depending on the collection area and on the products collected. For example, it is easy to prove that picking blackberries does not imply any risk to the species. However, if we are speaking of the roots of plants that mainly reproduce by stolons, it will take more work to prove that that species is not being affected by the wild collection. In such a case, scientific studies, the regulation of the collection by local authorities through establishing collection limits, and monitoring by the collection company itself, supervised by an inspection body may all be useful. Furthermore, the fact that a collection activity has been carried out in that area for a long time may serve as an indication that collection in that zone does not imply a menace to the habitat or to conserving the species.

#### Practical Example

In Croatia, collection permits are only required and issued by the authorities for endangered species. Also, to avoid the excessive collection of other species, the project manager must make a list indicating for each one of the species picked how it reproduces, in what season, and what part of the plant is picked and how the project will ensure that the species is conserved. Proving that the pickers are properly trained and that there is on-site annual inspection during critical plant collection periods both complement the species conservation plan.

That is to say that if the wild crop collection is certified organic, in addition to having to comply with the criterion of "non-application of prohibited substances", the main emphasis will be placed on the ongoing monitoring of the collected species and of the collection area. That includes:

- Periodically verifying the risk situation of the collected species

- Determining and developing proper collection methods and communicating them to the pickers
- Defining the quantities to be collected and when they may be collected, based on each plant's specific reproduction cycle
- Identifying the consequences of the collection activity on the whole ecosystem in the harvesting zones
- Defining measures to avoid the risks that collection may cause to the habitat.

The International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP) currently under development may be of use in introducing such measures, (<http://www.floraweb.de/map-pro/>).

#### *Animal Production / Apiculture*

As compared to the imports of products of plant origin, imports of organic animal products from third countries into the EU are still quite low. This category mainly includes honey and meat from extensive livestock production systems. The greatest risk in organic animal production (except for apiculture production) is the use of chemically-synthesized allopathic veterinary medicinal products, the failure to identify such use, as well as the scarce documentation on the herd or fold and the conventional feed. Above all, careful, sufficient, understandable, and verifiable documentation is a must for all animal production. That includes documentation on the animals' origin, treatments with medication given (to individual animals or to groups of animals), and the feed ration components, as well as on measures to recognize and minimize the important risk related to genetically modified organisms (in the feed, among other sources) reference to which is made below in another section.

Also, in organic apiculture, the feed given to the bees, the documentation and the use of chemically-synthesized allopathic veterinary medicinal products may be crucial aspects where risks of non-equivalence arise. Unlike in conventional animal production, in organic apiculture a conversion period is required after having used chemically-synthesised allopathic veterinary medicinal products. Therefore, it is of utmost importance to be able to prove that none has been used. Organic apiculture includes key concepts for the treatment and prevention of common diseases; the analysis of medications used, for example antibiotics, may help determine whether or not the unit is being run according to organic farming principles. In such cases special attention must be paid to the samples taken (ideally taken by the inspection body) and to their analysis in an accredited laboratory. If it is necessary to artificially feed the bees, the use of compliant honey substitutes must be proven.

#### *Genetically Modified Organisms (GMOs)*

As the use of genetic technology procedures and of genetically modified plants increases, especially in countries outside the EU, this complex of risks acquires more and more significance. In this respect, the main areas of risk identified are in primary agricultural seed

production, the adjacent production of GMO crops, the fodder used, and the additives in animal feed.

Especially when using high-risk crop seeds such as soy, cotton, and corn, for example, it is necessary to implement measures to guarantee that the seeds used are not genetically modified ones. Some possible measures are acquiring certified organic seeds - produced without genetic technology – or producing one's own seedbed. In addition, it is necessary to constantly ensure during the whole process that no contamination or commingling with conventional products and, therefore, probably with genetically modified products, occurs. When using machinery and equipment (planter, harvester, and cleaner) in both organic and conventional units, meticulous cleaning measures are as necessary as unmistakably identifying the products in question. Ongoing laboratory analysis and the use of the so-called quick tests are very important to guarantee production chains or production lines free of genetic engineering.

#### Practical Example

In southern Brazil, smallholders' organic soybean crops are cultivated using solely organic seeds produced in the same project. In addition, samples are taken from each lot of seeds used, then analyzed according to a specific testing plan. In that manner, possibly contaminated seeds may be identified and the lots in question discarded. A sample analysis is also made of the harvested lots based on a defined testing plan, to discover contamination during the harvesting and thus prevent them from reaching the organic market.

Laboratory analyses and quick tests also play an important role in impeding GMO contamination from neighboring GMO crops. If the organic crops are near GMO crops, it is necessary to maintain a minimum distance between the two production areas as a fundamental condition to minimize the risk of GMO contamination through pollen drift, accidental plants, and wild plant populations. The minimum recommended distances vary according to the type of crop: depending on the degree of maximum impurity, the suggested safe distance for soybean is fifty meters, for corn a few hundred meters, and for oilseed rape up to several kilometers. Other barriers such as hedges and woodlands may also reduce the risk of GMO contamination. Often, to respect the minimum required distances in risk areas, long-term crop planning as well as agreements with conventional crop farmers are required. Upon occasion, the proximity of broad extensions of land planted with GMO crops may make parallel organic crop production impossible because of high GMO contamination. To illustrate, that occurs with organic oilseed rape crops in some regions in western Canada.

When using conventional feed that imply a risk (for example, soybean and corn) or additives in the compound fodder (for example, vitamin B and vitamin E), the producer/vendor must be able to firmly affirm that it has not used substances obtained through genetic technology. At any rate, it is recommended that the inspection body verify such statements before the

products are used. To the extent possible, the best way to avoid GMO risks is to stop using conventional fodder or additives in the compound fodder.

Even among the phytosanitary products allowed in organic crop production, there are some (for example, a *Bacillus thuringiensis* preparation) prepared with the help of GMOs, which therefore cannot be used in organic production. Therefore, in this regard it is also important for the producer/vendor to unequivocally affirm that it is not using genetic engineering.

#### *Smallholder Group Certification*

In third countries smallholders are often certified in groups. In this certification system, at first all of the farmers are evaluated by the internal inspectors of the cooperative or of the export company. Therefore, the external inspection body does not visit each one of the production units; instead, it evaluates the effectiveness of the internal control system by inspecting a representative sample of the units. Such systems are highly efficient if properly applied. At any rate, they may be improperly used if the internal control system does not sanction infractions to the guidelines, for example those that may occur when attempting to fulfill business obligations to meet a determined export volume.

The guidelines for smallholder group certification were prepared by an IFOAM team (IFOAM 2003). To do so, the European Commission Guide for Evaluating Group Certification Systems had been consulted (European Commission, 2003).

An internal control system is generally based on the following main aspects:

1. All of the smallholders make a contractual commitment to organic crop production.
2. The system organizes internal inspections and training for the smallholders.
3. Internal inspections are followed by a standardized evaluation of the information gathered, which leads to a list of approved farmers, or, when serious non-compliances are observed, sanctions of the farmers in question.
4. The internal control system manages ample documentation (for example, contracts, smallholder production unit descriptions, maps, internal inspection reports, yield estimates and statements, list of approved farmers, external inspection reports).
5. The organic product flow is supervised and documented.

Also, sustaining resources, permanently trained independent competent internal inspectors, precisely determined responsibilities, adequate frequency of controls, and, once again, careful documentation are all essential to a reliable control system. Documents normally handled in an internal control system are: a project description, including an organizational chart and a product flowchart; a risk assessment; organic production standards; a contract with the farmer; organic production conversion procedures; internal inspection and approval procedures; sanction catalogue; production unit descriptions and inspection reports; a list of approved farmers; job descriptions; and work contracts with confidentiality clauses.



When an internal control system is improperly implemented, the following shortcomings may arise:

1. Insufficient effectiveness of the monitoring and control processes caused by a lack of training for the inspectors and for the rest of the personnel in the internal control system;
2. Internal inspectors' lack of independence;
3. Incomplete inspections (for example, only the organic crop parcel is visited) or lack of frequent control and monitoring (not all of the smallholders are inspected a minimum of once a year);
4. Insufficient application of sanctions for infringements;
5. Incomplete, hard-to-verify documentation.

Such deficiencies impede the possibility of the internal control systems being recognized by the inspection bodies, so they must be avoided at all cost.

However, at times the inspection body evaluation of the internal control system is not up to par. Some reasons for that are:

1. External inspectors with deficient skills and knowledge;
2. An overly superficial review of the on-site internal control system results;
3. Insufficient number of operators visited during external inspection;
4. Inadequate cooperation among the distinct external inspection bodies that operate in the region.

It is necessary to confront such risks with proper measures, such as intensive training, better documentation, and increased control frequency. The IFOAM training manuals on Internal Control Systems provide ample information (IFOAM 2004).

## **3.2 Processing**

### *Separation / Contamination / Commingling*

When both organic and non organic products are prepared at the same processing facilities, there is a potentially high risk of contamination and of commingling. Undoubtedly, the best way to minimize those risks is to use certain production lines exclusively for processing organic products (physical separation). However, that is not always possible. Therefore, when the same processing facilities are used for processing both conventional and organic products, the risk of contamination and of commingling must be minimized by using proper separation and cleaning measures. To do so, first, all the places and processes that present a risk of commingling must be analyzed. Then measures to prevent contamination, such as cleaning steps or system purges, are implemented. Such measures must be agreed upon with the inspection body. The implementation of cleaning procedures must be amply documented so that they may be verified during inspections. Sometimes the time and

expense involved in cleaning can be minimized through an optimum combination of several organic lots into one. The resources required may also be minimized by scheduling the processing of organic products after regular general cleaning, for example, by initiating organic production at the beginning of the week.

The Council Regulation on Organic Agriculture does not stipulate the cleaning substances and disinfectants to be used. Nonetheless contamination must be avoided in this area as well. Rinsing with potable water may be required, for example, after using very strong disinfectants and, if so, that must also be documented.

Another possibly high risk is the contamination of organic products due to the pest control measures that the company itself uses for its conventional products. Particular attention should be given to preventing contamination by the substances added to conventional produce to protect them when stored in transportation units (for example, screw conveyers) or to treat whole storage areas. In this case as well, the specific risks and necessary measures must be defined and the steps taken to avoid the contamination must be documented. Companies that process both organic and conventional products must orientate their whole pest control system towards organic criteria. To do so they must contemplate preventive cleaning and hygiene measures, train their personnel, eliminate structural deficiencies, and do exhaustive entry control. Furthermore, they must do ongoing monitoring of pests using baits and traps. And if it is necessary to implement direct pest control measures, they should use physical methods, not chemical ones.

#### Practical Example

A company in western Africa that processes both organic and conventional sesame no longer fumigates because it has implemented strict hygiene management and ongoing pest monitoring using pheromone traps.

#### *Diverging Inputs and Processing Aids*

The Council Regulation on Organic Agriculture Annex VI indicates the ingredients and processing aids allowed in organic products. It greatly limits the number of useable substances in food processing. Using reliable documentation, organic product companies must prove that solely regulation-compliant ingredients and processing aids were used in the preparation. Documentation of this nature includes, among others, the corresponding purchase invoices, current recipes as well as production records and the corresponding inventories. Moreover the company must clearly establish how it plans to respond to technological demands and to customer demands (for example, product baking quality and durability) using the permitted processing aids. To verify specifications, at times it is necessary to review the documentation for the conventional agriculture production; so, that documentation must also be exhaustive.

## *Records*

As has been seen, there are varied recording obligations associated with organic product processing at different levels. Such recording obligations are indicated either directly in the Council Regulation on Organic Agriculture or they are necessary for reasons of control efficiency. Processing companies must keep the mandatory records below, among others:

1. Certificate stating that the organic product suppliers have currently valid certification;
2. Statement that conventional components / ingredients are GMO-free;
3. Product entry control records and distinct component storage control records;
4. Current recipes;
5. Protocol for processed lots and their storage location;
6. Documentation of cleaning measures;
7. Invoices and delivery receipts.

Those various records must always be aimed at guaranteeing the integrity and traceability of the organic product processing. For control purposes, product flow calculations using the documentation for the processing must be done. The product records and incoming goods receipts, recipes, production lots, product inventories and outgoing goods receipts are used to verify if the quantity of goods produced in a determined timeframe is in accordance with the quantity of raw materials and additives acquired for such production. However, such records are not just necessary from a control perspective; detailed documentation may be used to discover deficiencies and to introduce measures for economic and qualitative improvements. That is to say, the company may obtain other direct benefits by implementing a meticulous recording system.

### Practical Example

Some third country processing companies purchase products from different producers and combine them in one lot (for example, sultan raisins or apricots in Turkey). Sometimes the goods of one of the producer are received and later not accepted, for example, because prohibited substances have been applied. Solely when the lot with the rejected goods can be identified by referring to an impeccable documentation, can the amount of product that must be blocked and removed be kept to a minimum. If the documentation is incomplete or if there is none, all of the lots processed up until then must be rejected.

## *Genetically Modified Organisms (GMOs)*

The growing use of genetic engineering also implies a growing potential for risks in the processing sector, for companies that are certified organic producers and for organic products alike. As is set forth in the Council Regulation on Organic Agriculture, to guarantee that the organic products in question are prepared without using GMOs or GMO derivatives, it is

necessary to evaluate if the conventional inputs and processing aids have been produced using genetic engineering. That may be ensured through laboratory analysis and commitment statements. Currently, the elements that generate the most risks in the preparation process are the components listed below:

1. Specific additives such as lactic acid, ascorbic acid, citric acid, calcium citrates, and tocopherols;
2. Microorganisms;
3. Vitamin B2 and vitamin B12;
4. Conventional plant oils (mainly soybean, corn, oilseed rape, and cotton), waxy corn starch, and fructose;
5. Flavors and
6. Enzymes, another important group of substances.

To the extent possible, it is important to totally avoid using components that create risks.

### *Labeling*

An essential element in all organic preparation is the proper labeling of organic products, to ensure that organic products can be differentiated from conventional ones at every step in their processing, and that the organic ones will therefore be treated as such. In that way, accidental changes or mixing are efficaciously prevented. Therefore, a processing company must take measures to always properly identify the goods. That starts with the incoming goods when the organic components can still be identified as organic, and then are stored in specific areas designated for them. During the following production processes, it is necessary to be attentive to the organic products being identified as such. To do so, they may be moved in “organic” recipients of a determined color or they may be placed in clearly differentiable packing materials. Sometimes it makes sense to reserve a specific color for organic products and for that color to be used throughout the whole process to identify and label the corresponding products and production equipment. Also, to the extent possible, different packing sizes may be used to differentiate organic quality from conventional quality. Finally, proper labeling at the end of the preparation process is fundamental. However, so is the labeling during the production process, for example, during the intermediate storage of semi-processed products, during which time it is important to reduce the risk of interchange or commingling.

### Practical Example

In a factory signs have been placed to indicate products with organic quality in the storage area and in the processing area. However, it was proven that the signs above the processing facilities had not been taken down when preparing conventional products. The inspection

body therefore concluded that the separation of organic products from conventional products could not be guaranteed.

### **3.3 Export**

#### *Labeling / Identification*

Clear identification is also indispensable in the trade/exportation of organic products. At all times organic products must be clearly identified as such in the different stages of the supply chain. Identification is done in two manners: 1. by precisely labeling each one of the containers and 2. by clearly indicating that the product is an organic product on the export papers. For safety reasons, to the extent possible, organic products must be identified as such on the packing as well as on the accompanying export papers. Throughout the whole exportation process, there are innumerable possibilities for an accidental substitution or interchange of products, principally in the diverse phases of the transportation process during which the product is handled by various transportation companies, through to where the product is stored, and then until it is finally packed in the transportation container. Badly trained personnel may easily confuse improperly labeled lots. It is recommended that exporters supervise the exportation process until their products are shipped or at least they should deliver clear indications of how to proceed with the organic products. Also the risk of an accidental interchange is considerably reduced if the export container is packed and sealed at the beginning of the transportation chain (for example, in the interior of the country, as that avoids any possibility of interchange on the way to the warehouses on the coast).

#### *Port Control / Phytosanitary Treatment*

In the past on several occasions in third countries there have been situations of organic products being mixed with conventional products before they were shipped at the ports. Precise on-site control where all of the documentation that accompanies the goods and the labeling on the packing is verified once again can effectively minimize such a risk. Along with the exporter's controls or those of its representative, a direct inspection by the responsible inspection body is essential.

In addition to verifying the identification of the goods, it is also necessary to ensure that the organic goods are not contaminated by containers sprayed with prohibited pesticides or mandatory phytosanitary measures before shipping. To do so, precise knowledge of each State's regulations is a must. Often it is necessary to request an authorization for exemption from fumigation with the routinely-used substances. If the application of synthetic chemical substances is waived, then of course a meticulous cleaning and hygiene treatment must be done on the merchandise and on the transportation container as well.

#### *Trade Agent Integration*

In the past situations of fraud have resulted in gaps in the control chain due to a lack of mandatory control by companies and trade agents. Thus it was possible to fraudulently claim that conventional lots were organic ones as they entered the EU, because the trading companies did not have to submit to any structured monitoring process by a certification body. Therefore, in the EU since July 1, 2005, trading companies must subject themselves to the inspection system. Also the control of merchants and agents plays an important role when evaluating the equivalence. So, it is especially important to review export processes involving more than one company and agent. If an organic product export agent processes the papers and accounts in its own name, it must be certified with a competent inspection body. Often that is still rejected, with the argument that the agent has no “physical contact” with the goods. It is recommended to work solely with certified agents and merchants.

### **3.4 Other Measures to Guarantee Equivalence with Regulation (EEC) No. 2092/91**

#### *Third Country Inspection Body Accreditation*

Regulation (EEC) No. 2092/91 sets forth that inspection bodies must comply with the conditions provided for in European Standard EN 45011 / ISO Guide 65. That standard defines the requirements for the inspection body structure and procedures. Compliance with EN 45011 seeks to ensure comparable, reliable work among the diverse inspection bodies. Standard compliance is verified through accreditation by an accrediting agency that is a member of the International Accreditation Forum (IAF) or of the agency European Cooperation for Accreditation (EA).

When choosing a third country inspection body, one must verify that the inspection bodies with which one is considering working comply with EN 45011 or ISO Guide 65, so that they can be then granted recognition by the competent authorities in the different member states of the EU.

#### *Third Country Inspection Body Work Method*

The manner in which third country inspection bodies work may also create diverse risk factors that may affect the quality and reliability of the organic certification.

For example, it is important for the inspection reports to be complete so that there is no hindrance to EU acknowledgment. The data sheet attached below gives some orientation on such matters.

The inspection reports must be countersigned by the companies. Some inspection bodies are accustomed to allowing the monitored company to fill in some of the content of the inspection report; that means there is no evidence that the inspection body is doing its work independently.

The quality of a third country inspection body may also be deduced by the frequency with which it conducts surprise inspections and by the number of samples it takes. Such controls

should be based on a risk assessment. All relevant information should be included in the inspection reports.

An essential condition for guaranteeing the quality of the monitoring and control process is how often inspections are made. A complete inspection should be made a minimum of once a year. Furthermore, it is necessary to ensure that when the inspection body subcontracts companies to make inspections, the latter comply with ISO Guide 65 or with EN 45011.

Moreover, valid, effective contracts are a fundamental part of an inspection system that works and that is equivalent. Contracts for indeterminate periods are unacceptable, as are gaps in the time periods covered by monitoring contracts.

Certain practices are unacceptable during the certification process. For example, inspectors may not directly invoice a controlled company and simultaneously be an advisor for it. Nor is it permitted to grant a certificate before the first inspection.

**4. Additional Data Sheet for the Application on Import Authorization**



**Additional Data Sheet**

**for the Application on Import Authorization**

Company ..... from .....

**1. Agricultural Production**

**Conventional Production Unit:**

**Yes**    **No**

Inspection  
Report  
Page:

**If you answered "Yes":**

- Physical separation by:

- Organizational separation by:

- Accounting separation by:

- Conventional production unit inspection date:

**Retroactive Recognition of the Conversion Period /**

**Reduction of Conversion Period:**

**Yes**    **No**

Inspection  
Report  
Page:

If you answered "Yes", explain:

**Seeds and Plants or Vegetative Propagating Material Used:**

**Organic:**

**Yes**    **No**

Inspection  
Report  
Page:

**Conventional, untreated:**

**Yes**    **No**

- If you answered "Yes", explain:

**Conventional, treated:**

**Yes**    **No**

- If you answered "Yes", explain:

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<b>Fertilizers and Soil Conditioners Used:</b>	Inspection Report Page:
<b>Phytosanitary Products Used:</b>	Inspection Report Page:
<b>Soil Fertility Conservation through:</b>	Inspection Report Page:
<b>Erosion Prevention through:</b>	Inspection Report Page:
<b>Wild Crop Collection:</b> <input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b> <b>If you answered "Yes",</b>  - Natural habitat stability guaranteed through:    - Conservation of the species in the collection area guaranteed through:	Inspection Report Page:



<b>3. Export</b>		
<p><b>Use of external transportation companies:</b>                    <input type="checkbox"/>Yes    <input type="checkbox"/> No</p> <p>- If you answered "Yes", commingling is prevented by:</p>		<p>Inspection Report Page:</p>
<p><b>Phytosanitary treatment at the border:</b>                    <input type="checkbox"/>Yes    <input type="checkbox"/> No</p> <p>- If you answered "Yes", contamination is prevented by:</p>		<p>Inspection Report Page:</p>
<p><b>Trade agent handles both conventional and organic products:</b> <input type="checkbox"/>Yes    <input type="checkbox"/> No</p> <p>- If you answered "Yes", separation of organic from non-organic products is guaranteed by:</p>		<p>Inspection Report Page:</p>

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