Certification of Organic Foodstuffs

In Developing Countries

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1. Introduction

In the European Union (EU) and the United States (USA), organic products are obtaining an increasing share in the market. Owing to this, experts are assessing that, by the year 2000, between 3 to 10 percent of the entire sales made in the marketing of foodstuffs in the European Union will be through the marketing of organic products.
In the European Union there are regulations, that define minimum requirements for the production, processing and import of organic products. In the United States, a skeleton law was passed for organic farming, the „Organic Foods Production Act“. This must however still be implemented by a regulation, which is in preparation at present. In Japan a regulation on organic agriculture will take effect by the end of March 2001.
All three rules in the industrialized countries prescribe certifications of the application of the instructed regulations.

The necessary inspection of farms and foodstuffs industries shall be carried out by independent institutions ("inspection bodies or certification bodies"), which can be state-run or private. The certificates issued by those institutions attest the conformity of the production systems to the prescribed standards within the inspected production units.

The superior economical quality of organic agricultural systems and the subsequent processing of foodstuffs essentially depends on the costs of the required inspections and certifications. In developing countries, still today the necessary inspections are mainly carried out by North American and European inspection bodies. The high costs however, limit the market access for small producers to the two most important export markets for organic products, namely the European Union and the United States of America. This kind of inspection and certification system may lead to new dependencies which is undesirable from the point of view of development policy.

The production, processing and export of organic products can also be inspected and certified through local inspection bodies in the so-called "third countries". Establishing such institutions and developing legal regulations for organic agriculture in developing countries is recently also being promoted in the framework of development cooperation projects.

This publication aims at describing the conditions for the work of local inspection bodies in developing countries, as well as to show the chances for support and co-operation.

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2 Basic Regulations

2.1 Council Regulation (EEC) No. 2092/91 on Organic Agriculture

The *Regulation (EEC) No. 2092/91 on Organic Agriculture and indications referring thereto on agricultural products and foodstuffs and the complying labeling of agricultural products and foodstuffs* came into effect on the first of January, 1993.
The regulation defines – as a directly applicable law - the minimum requirements for organic farming in all Member States of the European Union. It comprises, among others, standards for the agricultural production, the processing, the importation and the labeling of organic plant and livestock production. As of September 25, 2000, it was modified and amended by 31 subsequent regulations. Since August 24, 2000, organic livestock products have also been included in the Council Regulation and the use of genetic engineering in organically produced foodstuffs has been banned.

2.1.1 Standards on Agricultural Production

Article 6 and 7, as well as Annexes I, II, VII and VIII of the regulations contain requirements on agricultural production.

Organic production must take place in a unit/production unit that is *spatially* and *organizationally* separated from any possible conventional production. A parallel cultivation of organically and conventionally grown crops will be often inevitable under the special circumstances of agriculture in developing countries.

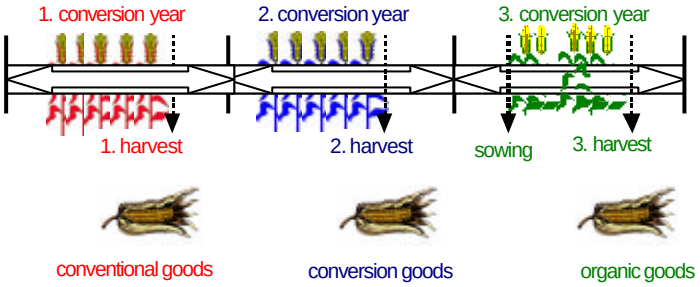
The demarcation between conventional and organic production must be however unambiguous and comprehensible. If export-cultures are grown on subplots of small scale farmers and simultaneously chemical-synthetic means are used for the production of staple food as corn and vegetables, the risk of an inadmissible application in the export-cultures is high.

2.1.1.1. Plant Production

In plant production, when changing from conventional to organic farming, a so-called conversion period of the parcels is of importance.

Annual crops need a two-year conversion period before the sowing of the first harvest of organic products. Perennial crops can only be labeled as organic products after a three-year conversion period (diagram 1). Nevertheless the harvest for annual and perennial crops can be marketed after a twelve-month period with reference to the conversion period.
The conversion period normally begins with the conclusion of an inspection contract between the inspection body and the producer in the third country. This contract must be laid out permanently.

A. Annual crops



B. Perennial crops

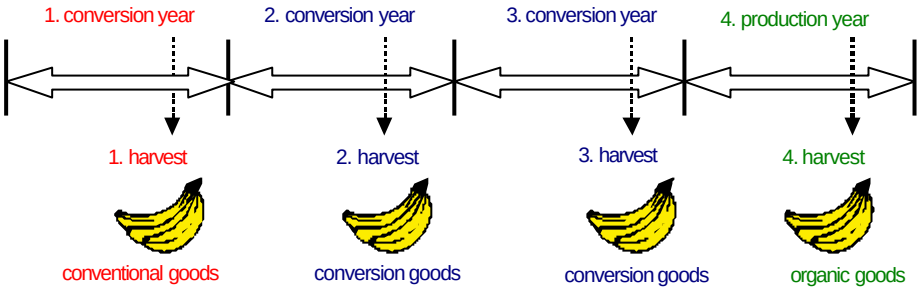


Diagram 1: Regulation of the conversion period of the parcels according to CR (EEC) No. 2092/91

The conversion period aims at allowing farmers to satisfy the EU requirements for organic farming. Essential to the plant production is to introduce measures for the maintenance and improvement of the soil fertility. In tropical and sub-tropical agriculture soil productivity can be particularly improved by introducing measures against erosion, appropriate crop rotational systems e.g. with leguminous plants and the application of organic fertilizers such as compost, farmyard manure and green manure.

In Annex II A of the Council Regulation products of supplemental use in fertilization and soil-conditioning in organic agriculture are listed.

In organic agriculture pathogenic agents and pests are to be suppressed through preventive measures as well as through physical and biological control. If required, the European Council Regulation allows a supplemental use of some fertilizers and pesticides that are listed in Annex II B, whereas the application of chemical-synthetic expedients is absolutely excluded.

The conversion period may be shortened in consideration of the previous cultivation. This, however, depends on a case to case decision by the inspection body. At the moment of importing the product to the EU, the competent EU-authority must have given the agreement to the shortage of the conversion period.

Genetically modified organisms (GMO) and GMO derivatives are banned in crop production (cf. chapter 2.1.1.4.).

2.1.1.2. Livestock Production

The publishing of the Council Regulation 1804/99 also included organic livestock production. It became effective on August 24, 2000. Annex I of the Council Regulation prescribes the production of bovine, porcine, sheep, goats, equidae and poultry (Annex I. B.) and of beekeeping (Annex I. C.). The organic production of rodents (e.g. rabbits) or deer (e.g. fallow-deer) has to fulfill the "standards accepted or recognized by the Member States of the European Union". Aquaculture is not (yet) included in the Council Regulation on Organic Agriculture.

Annexes I. B. (bovine, porcine, sheep, goats, equidae and poultry) and I. C. (beekeeping and beekeeping products) regulates, for instance, conversión periods, bought-ins and feeding, medication and breeding conditions. The most important regulations for livestock products are mentioned below. As the new regulations are very detailed, the regulation itself is to be consulted if necessary.

Livestock production forms an integral part of many agricultural holdings practicing organic farming. But, some exceptions are possible. Livestock may be reared conventionally on organic farms provided they are reared on a ¨unit¨ clearly separated, and a different animal species is involved. That means, that a simultaneous breeding of conventional and organic dairy cows is not possible, but to continue rearing conventional laying hens is, provided no organic hens are reared on the farm. Conventionally reared animals naturally produce conventional manure, which can only be used on organic plant cultivation according to the requirements of Annexes I.A. No. 2.1. and II.A.

In general the maximum livestock numbers per hectare are restricted (Annex VII) in order to guarantee, as far as possible, a close farm cycle between soil, plant and animal as well as to avoid ecological damage (contamination of the soil, of ground water and surface water). The objective of joining plant and livestock production is to maintain and increase soil fertility and therefore contributing to a sustainable agriculture. In ecofarming a maximum registration of nitrogen fertilizer of 170 kg of Nitrogen per year/ hectare should not be exceeded (Annex I.B. No. 7), including both conventional (Annex II.A.) and organic fertilizers.

Annex I.B. No.2 prescribes the conversion periods for all animal species except from bees, which regulations are laid down in Annex I.C. No. 2. The Council Regulation doesn't provide labeling for livestock production in conversion. This means, that organic livestock products can be labeled as such, only if they comply with the conversion periods fixed in Annexes I.B. No. 2.2. or 2.3. According to Annex I.C. No. 2 the conversion period for bees is one year.

The Council Regulation on Organic Agriculture only considers, under restrictive conditions, the acquisition of conventional means of production for livestock production.

Farms with eco-livestock production should fundamentally buy eco-animals. Annex I.B. No. 3 however considers that under certain circumstances conventional animals could be bought if

they are not available on the market. This applies for instance for chicks for broiler production (brought in conventional broilers must be less than three days old) and for pullets for the production of eggs (must not be more than 18 weeks old). Conventional bees may be acquired as swarms on their own (compliance with the conversión period required) or for the renovation of the apiaries (up to 10% of the queen bees and swarms, no conversion period required) (Annex I.C. No. 3).

Livestock must be fed on organically produced feedingstuffs. According to Annex I.B. the feed for the animals should come preferably from the same organic production unit. Up to 30% of the average feed formula (calculated in dry matter) can be from in-conversion feedingstuffs. That means, that the parcels have been complied with the basic rules of organic agriculture for at least 12 months prior to the harvest. If the in-conversion feedingstuffs come from the unit of the own holding, the share can increase up to 60% of the feed formula. Besides, conventional feed materials, listed in Annex II part C and D, can be used up to a limit of 10% (herbivores) or 20% (other breeds). Conventional bought-in feed material should not be genetically modified (cf. chapter 2.1.1.4.).

For bees (Annex I.C.) apply that the siting of the apiaries has to be cosen in a way that in a radius of 3 kms the bee pasture has to be mainly organically or extensively managed (Annex I.C. No. 4.2. b). Contamination from any non-agricultural production sources should be excluded. For hibernation the bees have to receive large quantities of honey and pollen supplies. For artificial feeding only eco-sugar syrup or eco-sugar molasses can be used if necessary. If they are unavailable in organic quality, it is possible to buy conventional sugar, provided that it is not genetically modified (cf. chapter 2.1.1.4.).

Disease prevention is especially significant on farms with organic livestock production. Nevertheless, if an animal fells ill, following regulations have to be complied with:

The Council Regulation prohibits the use of preventive allopathic chemically synthesized medicinal product. Phytotherapeutic and homeopathic preparations are first used during the treatment, and if they should prove not to be effective, chemically synthesized allopathic veterinary medicinal products or antibiotics may be used under the responsibility of a veterinarian. Growth-promoting or performance-enhancing substances as well as hormones or hormone like substances to control reproduction (e.g. induction and synchronization of oestrus), or for other purposes, are prohibited. The withdrawal period between the last administration of an allopathic veterinary medicinal product and the production of organically produced foodstuffs from the treated animal should be doubled in comparison to the legal withdrawal period. If the maximum number of treatments prescribed in the Council Regulation is exceeded, the animals in question or the products derived therefrom can't be sold as organic. The animals, subject to the agreement of the certification body, must once again undergo the conversion periods or must be sold as conventional products. Exceptions are: vaccinations, treatments for parasites and compulsory eradication schemes.

Systematical operations like cutting of teeth of hens or tail-docking of sheep are prohibited.

In the case of bovine, porcine, small ruminants and poultry livestock houses should guarantee a species-specific management (Annex I.B. No. 8). In Annex VIII of the Council Regulation minimum sizes for stables and yards were defined for these animals. Tying animals is prohibited. The prohibition of tying devices can be reversed on certain conditions such as security and protection of animals. Annex I.B. No. 8 also lays down detailed requirements for mammals and poultry.

The beehives should consist basically of natural materials and the bee wax for new frames should come, as far as possible, from organic production. The destruction of bees in the combs while harvesting is prohibited. In cases of infestation with Varroa jacobsoni following substances can be used: formica acid, lactic acid, acetic acid, oxalic acid, menthol, thymol and camphor.

For pest control, cleaning and disinfection only the products listed in Annexes II.B. and E can be used. According to the Council Regulation animals should have access to open air-runs.

The use of genetically modified organisms (GMO) and GMO derivatives is also prohibited in animal husbandry (see chapter 2.1.1.4).

2.1.1.3. Processing of Organically Produced Foodstuffs

Processing regulations on organic products are laid down in Article 5 and Annex VI of the Council Regulation (EEC).

All the ingredients of agricultural origin of an organic product must be organic. Only if an ingredient is unavailable as organic, it is possible to use conventional ingredients in the processing up to a certain maximum limit. Decisive is the relative share of agricultural ingredients in the weight at the time, when the product is processed. In Annex VI part C of the Council Regulation those conventional ingredients, which are not available in eco-quality in the European Union, are listed. The labeling and advertising of a product may refer, in the sales description of the product (e.g. organic herbal tea), to organic production methods only within a maximum level of 5% of conventional ingredients (Article 5 paragraph 3). If the labeling and advertising refer to organic production methods on the list of ingredients and apart from the sales description of the product, conventional ingredients can be used up to a limit of 30% (Article 5 paragraph 5a).

Annex VI of the Council Regulation not only lists conventional ingredients (Annex VI part C) but also a positive list of ingredients of non-agricultural origin (Annex VI part A) and processing aids (Annex VI part B).

During the processing of organic foodstuffs only a limited number of substances permitted as ingredients of non-agricultural origin (Annex VI part A) can be used. These are, for example, certain food additives, natural flavoring or flavoring extracts, drinking water, salt or microorganism preparations.

Processing aids (Annex VI part B) are used for technological reasons for the processing of raw materials, foodstuffs and their ingredients. Annex VI of the Council Regulation also restricts their use.

The use of genetically modified organisms (GMO) and GMO derivatives is prohibited in organic foodstuffs preparation (cf. chapter 2.1.1.4.). Organically produced foodstuffs and their ingredients can't be subjected to treatments involving the use of ionizing radiation.
For products of agricultural origin Annex VI does apply in its full extent. The only exception is the preparation of organic wine. Until now the regulations laid down in Annex VI don't apply. That means that for the preparation of organic wine all substances permitted as ingredients, according to the general food law, can be employed.
For the preparation of foodstuffs of animal origin only the prescriptions laid down in Annex VI part C has to be complied with until now. Parts A and B don't apply yet. Both for livestock products and wines state specific regulations or internationally accepted regulations for the preparation of organic products (i.e. Basic Standards of IFOAM) are to be met.

2.1.1.4. Genetic Engineering

According to the Council Regulation the use of genetic engineering is prohibited in organic agriculture.
The Council Regulation forbids on one hand the use of GMO. The term "GMO" is defined in Article 2, Council Regulation 90/220 as follows: an organism is "any biological entity capable of replication or of transferring genetical material. That means, that a genetically modified organism (GMO) is an "organism in which genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination". Examples for GMO are herbicide resistant soybean varieties or insect resistant BT-corn varieties.
According to the Council Regulation also the use of GMO derivatives is prohibited. A GMO derivative refers to "any substance which is either produced from or produced by GMOs, but does not contain them" (Article 4 No. 13 of the Council Regulation). Soy lecithin obtained from genetically modified soybeans is for instance a GMO derivative. GMO derivatives can be technically purified thus far that they do not longer contain any genetically modified hereditary material (DNA). In this case no analytical prove is possible.
The use of GMO and GMO derivatives are prohibited in agricultural production whether as seeds or soil conditioners (Annex II A), fertilizers (Annex II A), plant protection products (Annex II B), livestock or feeding stuffs (Annex II C and D). Their use in the processing of organic products, whether as food additives or processing aids (Annex VI part A, B and C), is prohibited.
According to the latest information the use of seeds, certain fertilizers and plant protection products (i.e. soy and œrn by-products, microorganisms), feed additives used in animal nutrition (i.e. vitamin B2 and B12, enzymes) in agricultural production need to be analyzed in particular. In the preparation of foodstuffs especially the use of corn and soy by-products or enzymes and flavorings has to be analyzed.

2.1.1.5. Control

In Article 8 and 9, as well as in Annex III of the Council Regulation on Organic Agriculture, the registration requirements for the inspection body and the application of the inspection system are described (cf. chapter 3).
In the European Union, the Member States are responsible for the implementation of the Council Regulation. Representatives of the EU-States meet regularly in Brussels in order to discuss the difficulties in the implementation of the regulation.
The EU-Member States could choose if the required inspections were to be operated by a inspections authorities or private inspection bodies. Mere government operated inspection systems can be found in Denmark and Spain whereas the majority of the EU-Member States opted for a partly state-run inspection system. This means, that approved private inspection bodies, which in turn are supervised by competent authorities, carry out the inspections "in situ".
A private inspection body resident in Europe may apply for EU-admission provided that it has an inspection system for organic agriculture ("Standard control system") and complies with the EN 45011. The official admission is only valid for that EU-Member State where the admission was applied. For instance a German inspection body can operate in Germany and Austria provided that it has applied for admission in both countries and has been accepted there. These EU admissions are not valid for non EU-Member States (third countries, cf. chapter 2.1.2.).
Annex III describes in detail the inspection requirements for farms, processing units and importers.

2.1.2 Regulation on Third Countries

Article 11 of the Council Regulation contains instructions concerning imports from non-EU Member States ("third countries").

2.1.2.1 Third Country Register (CR (EEC) No. 94/92)

Article 11 designates the drawing up of a third country register (diagram 2). Non EU-Member States, which have provided evidence, that the production methods and the inspection measures in the third country are *equivalent* to the rules of the Council Regulation, can be admitted onto that list. If a third country has not been admitted onto this list, the import authorization procedure under Article 11 (6) of the Council Regulation is required (chapter 2.1.2.2).

At the 14 January 1992 the third country register was inserted into the Council Regulation as regulation (EEC) No. 94/92. At present, only six third countries are world-wide entered into

this list, namely Argentina (inspections bodies: ARGENCERT and OIA), Australia (inspection bodies: AQUIS, BDRI, BFA, OVAA, OHGA and NASAA), Israel (inspection body: Plant Protection and Inspection Services), Check Republic (inspection bodies: Ministry for Agriculture, KEZ o.p.s.), Hungary (inspection bodies: Biokontroll Hungária, SKAL) and Switzerland (inspection bodies: Bio Inspecta AG, IMO and SQS). The inclusion of these countries is temporary.

Prerequisite for a registration into the third country register is a national legislation in the third country which contains regulations that are equivalent to the Council Regulation on Organic Agriculture. Hence this legal regulation must comprise minimum standards for production, processing, importing and for the inspection system in the respective third country.

The third country can apply for the registration into the third country register only after dismissal and transposition of this legal regulation through its diplomatic representation in Brussels.

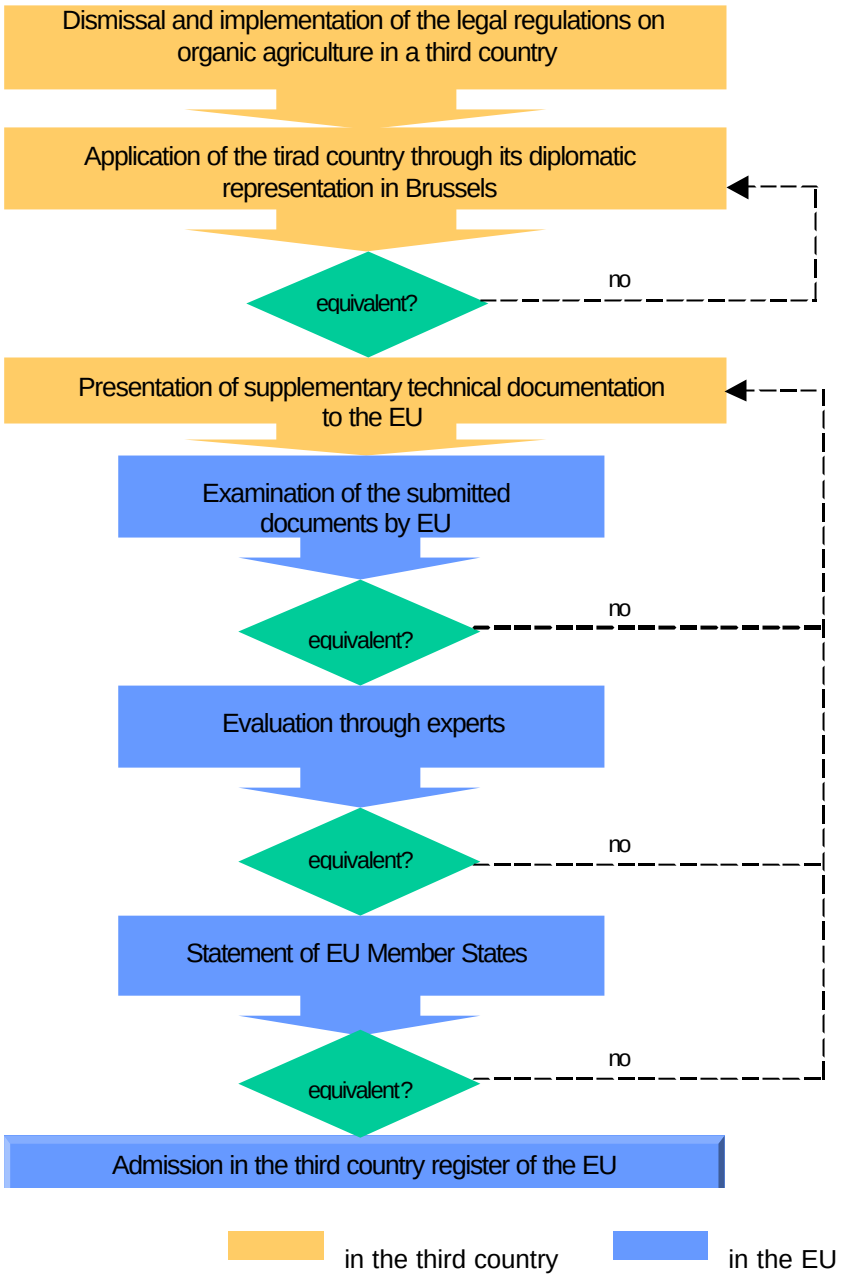


Diagram 2 Flow chart concerning the admission of a third country to the third country register according to CR (EEC) No. 94/92

Within six months after the application "supplementary technical documents" in one of the official languages of the European Union must be submitted to the European Commission. The requirements of these documents are laid down in Article 2, Paragraph 2 of the EC Regulation No. 94/92. They must include the following, specific contents:

1 *specification of type and, if possible, estimated quantities of agricultural products and food stuffs intended for export to the European Community under the regulation laid down in the article 11;*

2 information about the rules of agricultural production applied in the third country, viz:

- *the basic principles as set out in Annex I to Regulation (EEC) No 2092/91,*
- *the products permitted for use in the agricultural production, namely plant protection products, detergents, fertilizers or soil improvement products,*
- *the ingredients of non-agricultural origin permitted for use in processing agricultural products, as well as procedures and substances permitted in the processing.*

3 the rules of the inspection system and the organization of the implementation of this system in the third country:

- *the name of any authority responsible for inspection in the third country and/or the private bodies in charge of carrying out inspections,*
- *detailed rules for inspections on agricultural holdings and in preparation units, and the penalties which may be imposed in the event of infringements,*
- *the name(s) and address(es) of the authority or the body or bodies charged in the third country to issue certificates for imports into the Community,*
- *the necessary information about the inspection body and its measures for respecting the production rules and its inspection system,*
- *the list of processing units and exporters to the Community; the number of producers and the area in cultivation.*

4 If available, the on-the-spot examination reports established by independent experts on the effective implementation of the production rules and inspection rules.

(Article 2 of the Regulation (EEC) No. 94/92)

After the document check, usually on-site inspection follows through a EU-group of experts. This examination is regularly repeated after the admission of the third country.

It is important that the admission to the third country register requires a functioning, equivalent certification system in the respective third country. The setup of national inspection bodies in developing countries, that get its acknowledgement in the EU over import authorization in accordance with Article 11 (6) the CR (cf. chapter 2.1.2.2), is an important step on the way to the registration of a third country into this list.

As soon as the certificate, provided in the regulation (EEC) No. 3457/92, has been made out by responsible inspection body, named in third country register, products from organic

production are allowed to be imported into the Member States of the EU. The importer in the EU must take part in the control-procedure in the respective EU-Member State. Import authorization procedures are no longer necessary.

2.1.2.2 Import Authorization (Article 11 (6) Council Regulation (EEC) No. 2092/91)

According to Article 11 (6), importers to the Member States of the EU have to apply for an import authorization concerning organic products. This has to be done before the goods are marketed in the EU with reference to its organic production origin.
The products have to be produced according to production rules *equivalent* to those in the Council Regulation on Organic Agriculture in the EU. Furthermore, the inspection measures have to be of *"equivalent effectiveness"* to the inspection system intended by the Council Regulation. In addition to that, the inspection measures have to be applied *"effectively and permanently"*.

Consequently both the production rules and the inspection measures in a third country, may possibly differ from the requirements of the EC Regulation on Organic Production. Anr example is the duty to record laid down in the EC Regulation: in developing countries detailed records about the input products, its use and the product-sale on producer-level can hardly be introduced. In this case simple records can be equivalent, if a viable „internal control system“ exists (cf. chapter 3.2).

Diagram 3 schematically shows the course of an Import Authorization System.

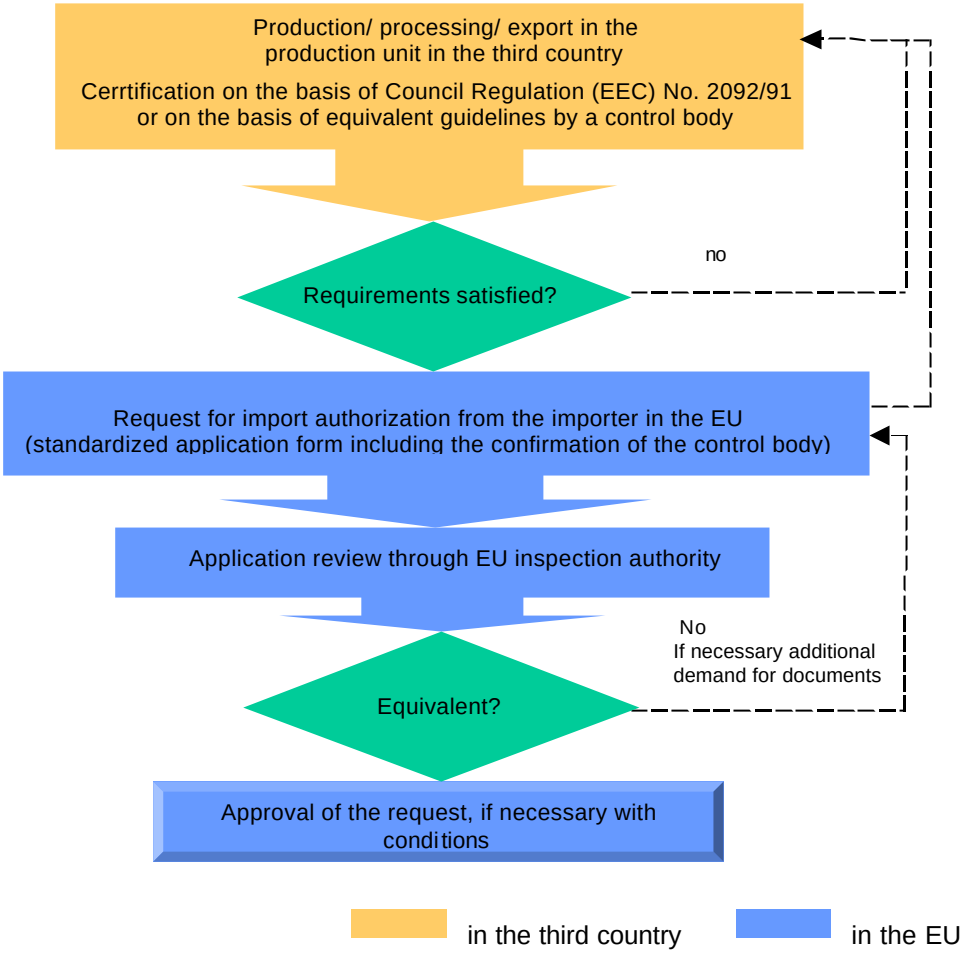


Diagram 3 Flow chart of the Import Authorization System according to Article 11(6) CR (EEC) No. 2092/91

After an inspection body has stated in the third country that the agricultural production, the processing and the export of the products from organic agriculture meet all requirements, an importer can apply for an import-authorization at the responsible authority in the EU.

The importing enterprise in the EU has to submit itself to the prescribed inspection system, if this has not already taken place.

The importing enterprise in the EU has to prove the equivalence of the production and the control measures in the import authorization request and justify deviations from the Council Regulation on Organic Agriculture in the third country. The responsible inspection body must confirm the statements made in the application as well as the actual and continuous realization of the control measures in the third country.

Complementary to the standardized application form additional records should be submitted regularly to the supervision authorities in the EU, for instance copies of the contracts between the inspection body in the third country and the farms and co-operatives, respectively, the

processing enterprise and the exporter. Also copies of the current inspection-reports are often required.

From the 1st July 1999 the inspection bodies working in third countries have to fulfill the conditions of the EN 45011 and the ISO-Guide 65, respectively (cf. chapter 3.4). EN 45011 and ISO-Guide 65 are internationally recognized standards which define how an inspection body has to work. Corresponding evidence can also be ordered by the inspection authority.

The inspection authority, which is responsible for the importer, can notify the application negative or positive. In cases of doubt, it is possible for the authority, according to Article 11 (6) of the EC Regulation, to appoint a committee (Article 14) with representatives of the EU-Member States and the EU Commission.

An authorization is normally limited to one year. Within this year the EU-importer can import a fixed quantity of organic products into the EU from the exporter mentioned in the application form. After the import authorization is given, a new proposition has not to be put for each lot of products. However, the authorization refers only to the importer named in the application. If organic products from a third country are imported by several importers within the EU, each of these importers has to make an application for an import authorization, which is supplemented by the affiliated documentation.

After giving the import-authorization, each lot of products that is imported into the EU, must be accompanied by a standardized product certificate (diagram 4). This product certificate should be made out by the inspection body working in the third country. It is useful that the original of this certificate is enclosed to the documentation of the merchandise (e.g. bill, Certificate of Origin, Bill of Lading).

2.2 Organic Foods Production Act

2.2.1 Regulations for Production and Processing of Organically Produced Goods

The United States Federal Organic Foods Production Act is aimed to set up uniform national guidelines on organic products, in order to protect consumers from being misled and to facilitate the trade of organically produced foodstuffs within the U.S.A.

In some states specific regulations, based on the basic regulations of the federation, have been established. An example of this is the California Organic Foods Production Act from 1990. At present a regulation is in preparation in the US which specifies the requirements of the Federal Organic Foods Production Act.

EUROPEAN COMMUNITIY
Certificate for import of products from organic production

<table>
<tr><td colspan="2">1. Body issuing the certificate(name and address)</td><td colspan="2">2. Regulation (EEC) No. 2092/91, Article 11

Reference number of the certificate</td></tr>
<tr><td colspan="2">3. Exporter of the product (name and address)</td><td colspan="2">4. Control body * (name and address)</td></tr>
<tr><td colspan="2">5. Producer or processor of the product * (name and address)</td><td colspan="2">6. Country of dispatch</td></tr>
<tr><td colspan="2" rowspan="2">7. Consignee of the product in the Community (name and address)</td><td colspan="2">8. Country of destination</td></tr>
<tr><td colspan="2">9. Address of the place of destination *</td></tr>
<tr><td colspan="3" rowspan="3">10. Marks and numbers, Container No(s),Number and kind. Trade name of the product.</td><td>11. Gross mass (kg)</td></tr>
<tr><td>12. Net mass(kg)</td></tr>
<tr><td>13. Alternative units *</td></tr>
<tr><td colspan="4">14. Declaration of the body issuing the certificate
This is to certify that the products designated above have been obtained in accordance with the rules of production and on inspection of the organic production method, as set out and monitored by the control body mentioned in box 4.</td></tr>
<tr><td colspan="4">15. Additional declaration remark (if appropriate)</td></tr>
<tr><td colspan="4">16. Place of issue of the certificate Stamp of the issuing body

Date

Name and signature of authorized person</td></tr>
</table>

*Explanatory notes

Box 4: Control body for monitoring compliance with the rules on organic production methods.
Box 5: The firm which carried out the last operation (processing, packaging, labelling) on the batch.
Box 9: The address of the firm where the batch will be delivered, if different from the address in box 7.
Box13: e.g. volume in liters in case of liquids, to be given, where appropriate, in supplement to the declarations in boxes 11 and 12.

Diagram 4: Product Certificate according to CR (EEC) No. 3457/92[1]

[1] A new form will probably replace this product certificate by August 2001. The revised version wasn't available before this brochure went to press.

It will replace the legal regulations, that exist in several federal states at present.

In contrast to the EU-Regulation on Organic Agriculture, in the U.S.A. the application of the firmly established regulations is not limited to organic foodstuffs. In addition, the application of the firmly established regulations is not limited to organic foodstuffs.

With annual and perennial farm crops, there must be, according to the prescribed regulations, no use of forbidden substances and materials during the three year period before certification. Before certification, an "Organic plan" for the production or processing and wholesale must be drawn up and must be submitted to the inspection bodies. In these plans, the measures are documented which are to guarantee the observance of the legal regulations.

The legal regulations in the U.S.A. also require inspections through independent, recognized inspection bodies.

2.2.2 Third Country Regulation

The regulations in the U.S.A. ensure that in the United States imported agricultural products are permitted to be sold with reference to "Organic Cultivation", if a government arrangement between the U.S.A. and the third country in question has been signed or if on a national level the *equivalence of a certification program* by an inspection body in a third country has been recognized.

In the latter case, in the United States, inspection bodies ("certification programs") are examined which is different from the procedure of an import authorization required by the EU-Regulation on Organic Agriculture. In future the recognition will be centrally carried out by the United States Department of Agriculture (USDA) in Washington that will be in charge of a register of inspection bodies, which are considered equivalent.

Specific applications from importers, given in the Import Authorization System, according to Article 11 (6) of the European CR on Organic Agriculture are not necessary in the U.S.A.

2.3. Codex Alimentarius

The Codex Alimentarius is a collection of internationally recognized adopted food standards (ALINORM) presented in a uniform manner. The Codex Alimentarius Comission prepares the different chapters of the Codex and government circles vote its content after being submitted worldwide to consultation.

The Codex Alimentarius Commission works on a mandate of the FAO and the WHO. The Codex isn't an international or national valid legal regulation. Worldwide it should be consulted as a guideline and reference for the elaboration of national regulations and therefore

contribute to an international harmonization. The Codex not only guarantees protection for the consumers against deception and fraud but also facilitates international

trade.

In 1999 the Codex Alimentarius Commission published guidelines for the production, processing, labeling and marketing of organic foodstuffs (CAC/GL 32-1999). Until now, these guidelines only include unprocessed products of vegetable origin and processed organic foodstuffs, basically of vegetable ingredients. The Codex is printed in the annex of this publication. At present, the guidelines for organic livestock products are being prepared.

Thanks to the publication of the guidelines of the Codex Alimentarius there now exist criteria to evaluate, for instance, the equivalency required by the Council Regulation on Organic Agriculture (cf. chapter 2.1.2.1. and 2.1.2.2.). That is why the guideline CAC/GL 32-1999 is an indispensable instrument for the preparation and evaluation of guidelines from national certification bodies for organically produced foodstuffs and for the legal regulations in developing countries.

2.3.1. Regulations for Production and Processing of Organically Produced Goods

The Codex Alimentarius resembles the Council Regulation on Organic Agriculture in structure and content.

Section 1 defines the scope. That means unprocessed products of vegetable origin and processed organic foodstuffs, basically of vegetable ingredients.

Section 2 regulates the labeling. Likewise the Council Regulation on Organic Agriculture, the Codex Alimentarius defines that products referring to organic production methods must at least contain 95% of organic ingredients and that only certain ingredients of non-agricultural origin (Annex 2, table 3) and processing aids (Annex 2, table 4) can be used (cf. chapter 2.1.1.3.). Conventional ingredients of agricultural origin only can be used if they are not available in organic quality (section 3.4.).

Section 4 in conjunction with Annex 1 and 2 defines the basic standards for organic agriculture and the processing of organically produced goods. The regulations for the production and processing of organically produced goods are to a great extent similar to those of the Council Regulation on Organic Agriculture. The use of genetic engineering is prohibited (cf. Chapter 2.1.1.5.).

The requirements for inspection and certification systems are stated in section 6 and Annex 3.

2.3.2. Regulations for the Import of Organically Produced Goods

Section 7 prescribes the basic standards for the import of organically produced goods. It states that the

goods subjected to these guidelines only can be imported, if an authorized certificate, which shows the compliance with the Codex requirements, accompanies the goods. Provided that the legal regulations of the import country satisfy the Codees standards, it can demand from the export country a detailed proof of the equivalency of the national regulations with the CAC/GL 32-1999 guideline. Also on-the-spot examinations can be carried out in the export country.

3. Inspection and Certification of Organically Produced Products in Third Countries through Local Inspection Bodies

3.1 Basic Concepts

The inspection and certification of organically produced goods in third countries can be carried out through *direct certification* by inspection bodies with admission in the European Union or the U.S.A. (cf. chapter 3.1.1), as a *co-certification* (cf. chapter 3.1.2) or through local inspection bodies in third countries *(local certification)* (cf. chapter 3.1.3, diagram 5). Only in the EU it is designated, that inspection bodies from third countries have to be supervised (cf. chapter. 3.1.4).

3.1.1 Direct Certification

With direct certification, farms or small scale farming co-operatives, as well as processors and exporters of organic products are to be inspected by supervisors from inspection bodies accredited in the EU or U.S.A. (cf. diagram 5). The internationally active inspection body can also employ local staff in the case of direct certification.

In the Import Authorization System of the EU, according to Article 11 (6) of the EU Regulation on Organic Agriculture (cf. chapter 2.1.2.2), the inspection body authorized in the EU is listed in the application from the importer as inspection body in the third country. The inspection body confirms the equivalence of production and inspection regulations and provides, in the case of imports, the required product certificate according to the CR (EEC) No. 3457/92 (cf. diagram 4).

3.1.2 Co-Certification

In the case of co-certification, an inspection body not recognized at the importers location comes into action in a third country (cf. diagram 5). These inspection bodies can be locally in

a third country or internationally operating certification organizations. The required inspections on production, processing and export level would be carried out by an independently working inspection body in the third country, not recognized in the country of the importer.

The certification of an inspection body in a third country has to be examined by the co-certifying body by means of another certification decision and will be confirmed if all requirements are fulfilled.

In the request for an import authorization in the EU, usually only the co-certifying inspection body is mentioned. This inspection body provides the required confirmation and the product certificates (cf. diagram 5).

3.1.3 Local Certification

Inspections and certifications in third countries can also be carried out by local inspection bodies, which are resident in the third country (local certification).

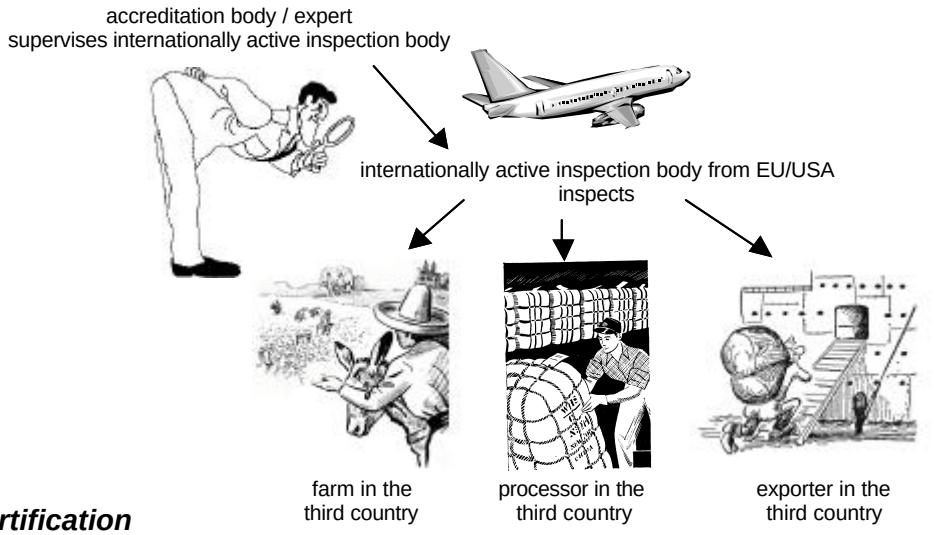
An inspection or certification body in a third country

- operates without capital participation of international organisms or at least with international capital participation below 50%
- takes decisions on certification in the third country fully and independently and
- are recognized in the import countries without the formal collaboration of internationally operating certification bodies

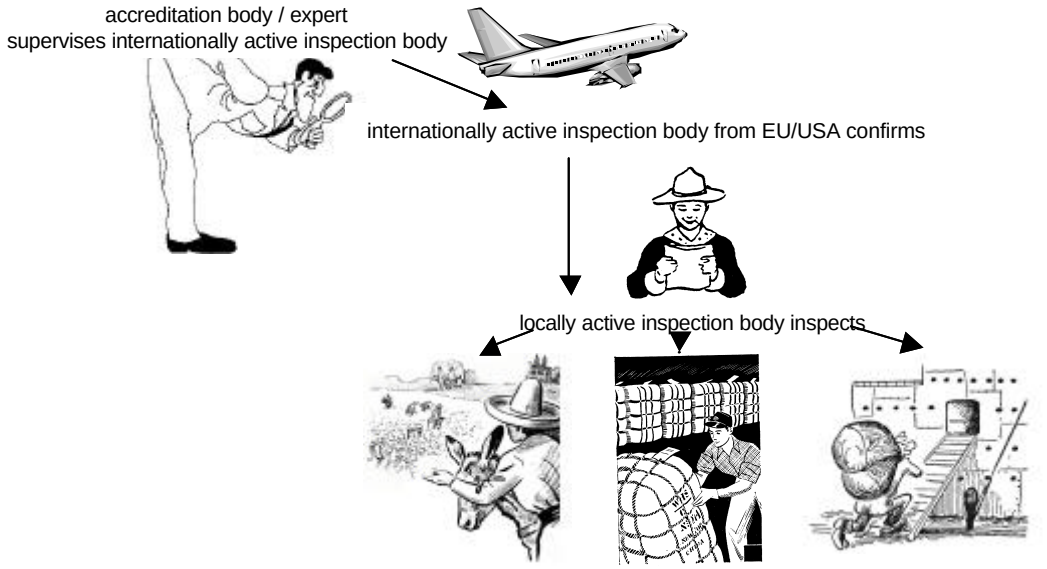
Inspection and certification of agricultural production as well as processing and export are then *independently* implemented on the basis of equivalent production rules and inspection measures.

In the EU, the local or regional inspection body in the third country is named as responsible institution in the request for an import authorization. It confirms the equivalence in the framework of the application and issues the necessary product certificates (cf. diagram 5).

A. Direct Certification



B. Co-Certification



C. Local Certification

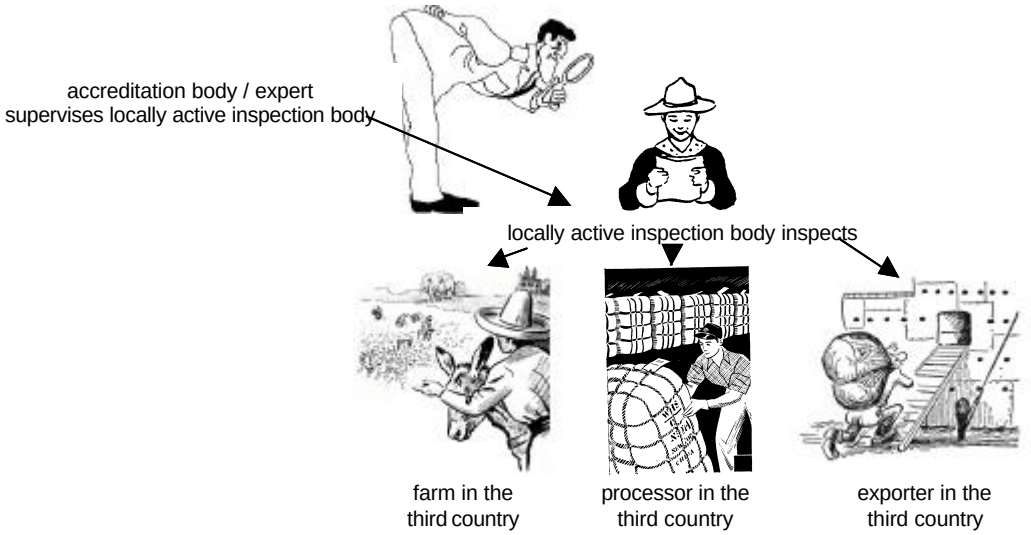


Diagram 5: Direct certification, co-certification and certification by local, supervised inspection bodies in a third country

3.1.4 Supervision of Inspection Bodies in Third Countries

Beginning of 1998 the supervision authorities in the EU introduced a supervision of all inspection bodies active in third countries and named in the framework of Article 11 (6). This supervision must be proved by each inspection body which works in non-EU Member States. These are internationally active inspection bodies with authorization in the EU or the U.S.A. as well as regionally active inspection bodies with headquarters in third countries.

Usually the supervision system is carried out *in reference to the inspection bodies*. Herewith, the organizational implementation of the inspection system, the existing documentation, the staff and the bookkeeping are checked at the inspection body („*office-Audit*"). Spot check inspections on production-, processing- and export-business with involvement of local inspectors add to this evaluation *(„witness-Audit*"). The inspection is effectuated on the basis of a standardized check list stipulated by the EU-inspection authority.
The supervision can be carried out by accreditation bodies (option 1), accordingly qualified authorities in third-countries (option 2) or by experts recognized by the EU inspection authorities (option 3). Accreditation institutions should be member in the international professional organizations *International Accreditation Forum* (IAF) and *European Co-operation of Accreditation* (EA), respectively.

Experts that work individually or on behalf of accreditation bodies have to fulfill the following requirements:

- practical and theoretical experience in the application of the EC Council Regulation;
- successful final examination of a training-course about the ISO Guide 65 / EN 45011 held by an accreditation institution, that is member in the EA and the IAF, respectively;
- declaration on the independence towards the inspection body to be evaluated and to operators to be certified by that body;
- exclusion of competition: in the concerned countries and regions is neither allowed to the expert, linked enterprises and accreditation bodies to carry out inspections /certifications in the field of Organic Agriculture nor to offer consultation services.

3.2 Planning and Realization of Inspections and Certifications in Third Countries

In the taking up of the inspection system, it is important to consider the inspection of the whole chain - from the production over the processing to the exporter. This has to be proved by appropriate reports and certifications.

The inspection begins with a description of the production unit, which is submitted to the inspection system (blue prints of the area and of the buildings, history of land-use, plans of the processing equipment, product flowcharts etc.). This unit (e.g. farm, co-operative of small scale farmers, processing or export enterprise) has to be clearly separated spatially, technically and organizationally from conventional production units.

Subsequently, a first inspection is conducted by an inspector commissioned by the inspection body. This inspection serves to give information about the requirements of the guidelines and to point out existing deficits.

The inspector‘s report, which is signed both by the inspector and the responsible for the inspected unit, serves as a basis for the certification decision by the inspection body.

In the following years, inspections are annually conducted by inspectors of the inspection body, leading to another report and a renewed certification decision from the inspection body.

The certificate issued by the inspection body can, in the case of agricultural units, be issued to farms that are in the conversion period, as well as to enterprises, which produce recognized, organic products (cf. diagram 1). In the case of processing or export enterprises there is no conversion period, but conversion goods might be processed and exported.

Also a smallholder-cooperative, that has an own legal status and internal regulations for its members, can be considered as business-unit in third-countries. Therefore inspections can be prepared in smallholder-co-operative without inspecting each single member of this community organization for cropping has to be inspected by the inspection body in charge (diagram 6).

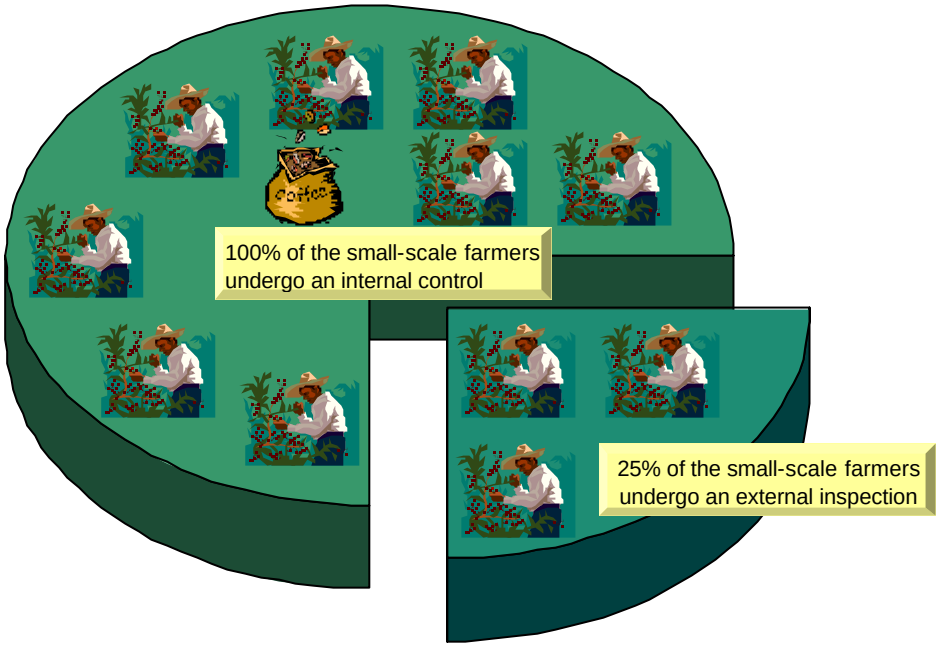


Diagram 6: Inspection procedures in units of small-scale farmingo co-operatives

All small-scale farmers have to undergo an internal control at least once a year. Prerequisite is that an internal control system has to be introduced and realized in the co-operative. But it must not be a consulting system. The typical documentation of an internal control system consists of contracts between each farmer and the cooperative, descriptions for all farms, that produce organically within the co-operative, furthermore internal inspection reports and a documentation of the co-operative internal sanctions, that are applied to farms which do not (totally) satisfy the requirements. All small-scale farms must be internally controlled at least once a year. The external inspection body checks the documentation and effectiveness of this system and selects a spot check of farms for inspection. The quota of the inspected farms depends, among other reasons, on the quality of the internal control-system. The results of the internal inspections which are regularly carried out on the basis of the rules of production, must be carefully documented.

3.3 Quality Management for Inspection Bodies: ISO 65 and EN 45011

In May 1985, the *New Approach to Technical Harmonization and Standardization* was passed by the European Council. Aim of this resolution is to widen the inner-community trade in the EU and to increase confidence to the quality of organically produced goods and services. Up to the year 1985 detailed regulations had been laid down in EU-guidelines and in the Council Regulation itself. The application of the *New Approach* enabled a new type of legislation, which only fixes the basic requirements in EU-guidelines and regulations and furthermore refers to harmonized technical international and European standards.

Technical specifications and standards like that are elaborated world-wide by the *International Organization of Standardization* (ISO) and are transferred to the European level by the European standardization organizations CEN and CENELEC.

In different EU-guidelines and regulations it was now embodied that inspection and certification bodies have to fulfill internationally recognized standards.

3.3.1 CR (EEC) No. 2092/91 and ISO 65 / EN 45011

In 1995 it was laid down for the EC Council Regulation on Organic Agriculture that from the 1st January 1998 authorized inspection bodies have to meet the conditions of the European Standard EN 45011 ("Guidelines for bodies operating product certification"). The EN 45011 corresponds to the ISO-Guide 65 from 1996. Both the ISO-Guide 65 and the EN 45011 describe the requirements on the fundamental structure and procedures of certification bodies. They are “intended to ensure that certification bodies operate ... in a consistent and reliable manner”. While the Council Regulation speaks of "inspection bodies", in the ISO-Guide 65 and the EN 45011 the term "certification bodies” is used. Both terms are synonymous. Furthermore in both the ISO-Guide 65 and the EN 45011 the term "product" is used in the widest sense and includes procedures. This is important, because certification systems in Organic Agriculture are based on an evaluation of production procedures.

Now certification bodies that inspect and certify the conformity of product standards (=guidelines for Organic Agriculture) have to subject themselves to standards. Keeping with the guidelines of ISO-Guide 65 and EN 45011, respectively, permits that different certification system are comparable and are run in a reliable manner.

In December 1997, the EU-Member States came to an agreement that also inspection bodies working in non-EU-Member States have to fulfill the ISO-Guide 65 and the EN 45011, respectively. This is consistent from the point of view of the EU-Member States, since the EN 45011 derives from international standards of the International Standards Organization (ISO) which has attained worldwide validity and ensures a harmonization.

Diagram 8 schematically shows the interaction between the requirements of the Council Regulation (EEC) No. 2092/91 and those of ISO-Guide 65 and EN 45011.

In the yellow block of diagram 8, the activity of an inspection/certification body is presented, as was described in fundamentals in chapter 3.2. The inspection body inspects producers, processors, importers and exporters of organically produced foodstuffs on the basis of guidelines for Organic Agriculture.

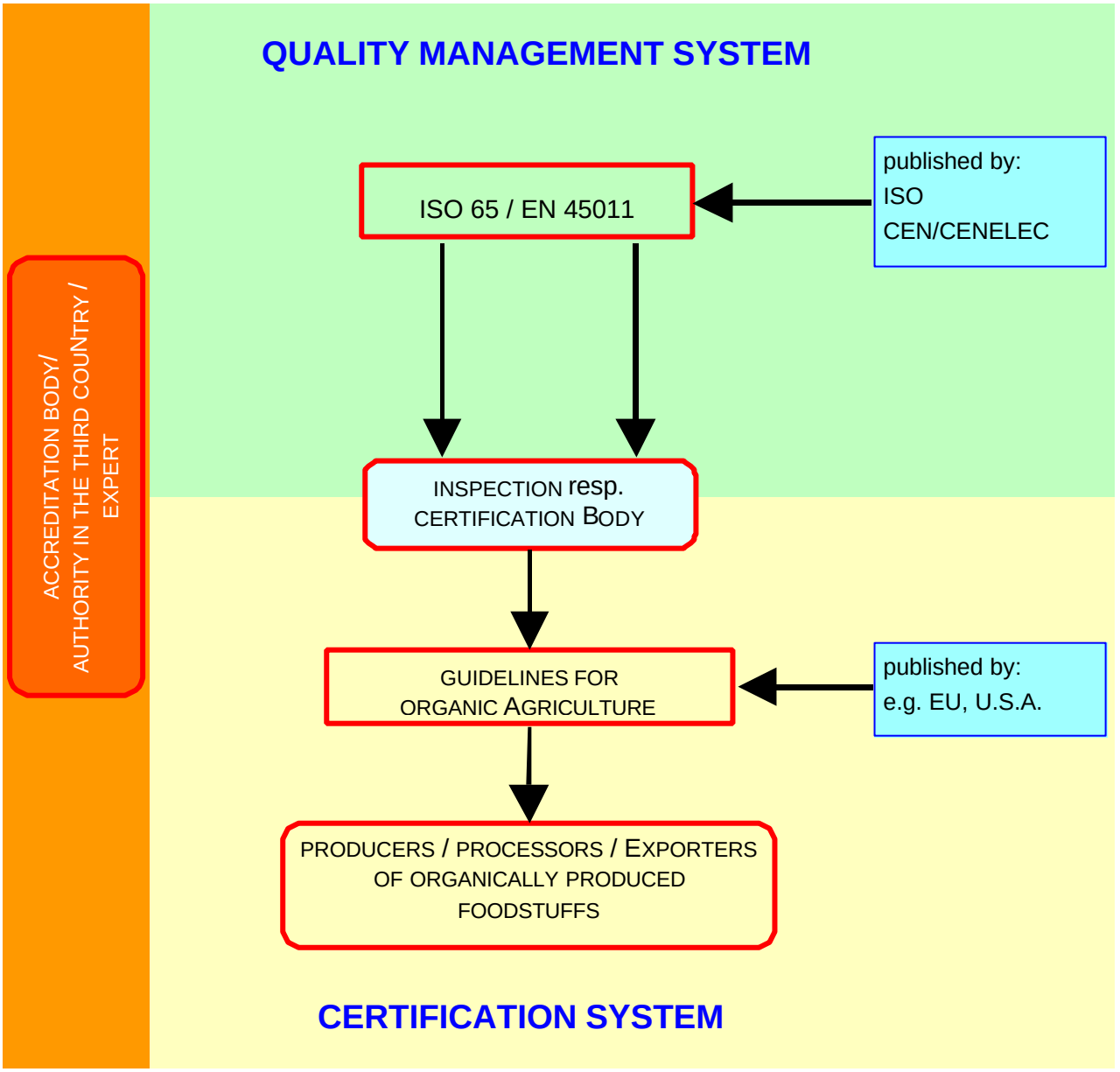


Diagram 8: Council Regulation (EEC) No. 2092/91 and ISO 65 / EN 45011

If the inspection body becomes convinced that the method of agricultural production and the products are consistent to the underlying guidelines, a certificate can be issued.

The inspection body itself must meet the conditions of the ISO-Guide 65 and the EN 45011, respectively, and (for this purpose) has to install a quality management system (green block of diagram 8).

The certification and quality management system have to be described in handbooks (cf. chapter 3.4.2.4) and must be applied in daily work.

The evaluation of the requirements of article 11 (6) of the Council Regulation is done with the aid of the supervision described in chapter 3.1.4 (orange block of diagram 8). Accreditation bodies should be member in the International Accreditation Forum (IAF) or in the European Co-operation of Accreditation (EA). This is not yet the case for a series of national accreditation bodies working in developing countries.

3.3.2 Elements of the ISO 65 / EN 45011

Subsequently, the most important elements of the ISO-Guide 65 and the EN 45011 are introducingly presented. Subsequent references can be taken from the text of the standards (cf. references) and from the check list mentioned in chapter 3.1.4.

3.3.2.1 Basic requirements at the structure and organization of a certification body

The ISO-Guide 65 and the EN 45011 define that a certification body has to be impartial and non-discriminatory. This means that the conditions must be clear for each person interested in an inspection and certification (e.g. guidelines, table of tariffs, sanction catalog) and must be applied in that way, that the participation of certain groups is not particularly relieved or impeded. An inspection body for example, that would like to offer its service only to operators that are member in a certain association of organic farmers, would discriminate those petitioners, that are not members.

The certification body must dispose of a legal entity. The organizational structure of the body must ensure its impartiality. This means that an inspection body must not offer any service, that could cast doubt on its objectivity (e.g. marketing promotion of organically produced foodstuffs, consultation activity for inspected and certified enterprises/ operators). Other factors that could negatively influence the impartiality are financial dependence (small customer base with lacking external funding) and personal relationships with the clients.

The organizational structure of the inspection body is presented by an organization chart (diagram 9).

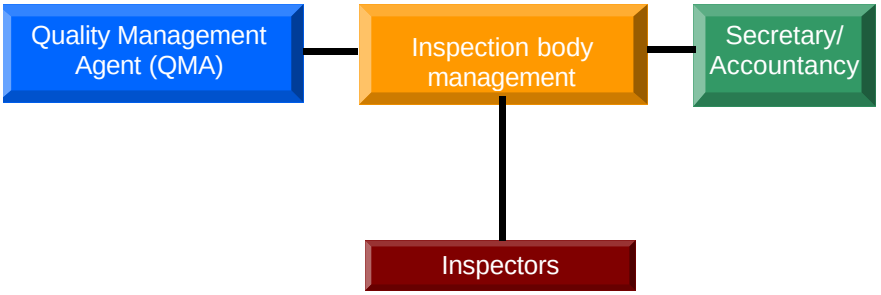


Diagram 9: Organization chart for an inspection body for organically produced foodstuffs

Each position must be safeguarded by a substitute - double functions are quite possible. The areas of responsibility of the personnel must be determined. While the management of the inspection body and the inspectors are responsible for the carrying out of the certification procedure, the quality management agent (QMA) is in charge of the quality management system. He reports regularly to the management on the state of implementation and has to propose improvements. The management decides to what extent modifications are necessary and whether they should be introduced.

The ISO-Guide 65 and the EN 45011 require that the basic regulations for the activity of an inspection body (e.g. guidelines) must be developed that way that the participation of the interested parties (e.g. producers, processors, consumer protection, science) is guaranteed. Both standards proceed from the assumption of a compensation of interests between conflicting positions.

3.3.2.2 Personnel

Competent personnel is the most important "capital" of a certification body.

First, minimum-requirements are to be defined and documented for the qualification of the personnel. These will usually be different for the management, the QMA and the inspectors in the field of agricultural production, processing and export of organic products. Contractual agreements must ensure, that the personnel knows and follows its rights and responsibilities, works objectively and safeguards confidentiality.

A documented procedure for training guarantees that new employees can cope with their tasks. A procedure for courses of training and further education provides a steady further qualification.

As documentation of the qualification, training and experiences of the employees standardized personnel files should be used to summarize the required information.

It applies to sub-contractors (e.g. chemical laboratory for the analyses of residues of pesticides), that in principle they have to satisfy the conditions of the corresponding

international standards. For a chemical laboratory for instance, it concerns the ISO-Guide 25 and the EN 45001, respectively.

3.3.2.3 Certification system

An important principle in the certification procedure is, that to the interested party and the applicant, respectively, the requirements for a certification are known and transparent - any information deficits should be cleared, as far as possible.

The inspection body may carry out its inspections and come to a certification decision only on the basis of the applied guidelines. Therefore it cannot use further criteria, that were not known to the applicant before. All criteria must be checked during inspection.

After the formal application of the interested party an evaluation of the unit is carried out by the certification body (first inspection). During an inspection the inspectors should only register and document information (”fact-finding”). The inspection report should contain comprehensible information concerning all requirements of the guidelines.

Afterwards the report will be evaluated in the certification body. The decision on a possibly certification is done by a person or a committee that did not participate in the inspection. If the requirements are satisfied, a certificate is issued.

The certification body must have a documented procedure, under which circumstances a certification can be granted. This procedure should also lay down, how a certification could be extended (e.g. at the admission of new methods of agricultural production) and under which conditions certifications are suspended or withdrawn (e.g. in the case of fatal offences).

During the term of the certificate which is normally issued limited in time, further announced and non-announced inspections are carried out (*supervision*).

A standardized procedure for the treatment of objections and complaints enables that protests can be treated objectively.

According to the ISO-Guide 65 and the EN 45011, respectively, the certification body is obliged to publish information to the basic certification requirements, to inform its customers about alterations of the guidelines and procedures and to offer a list of certified operators and the respective products.

3.3.2.4 Basic principles of a Quality Management System

The aim of a Quality Management is to continuously guarantee from the beginning that mistakes are avoided, because they cause expenditures. Therefore Quality Management (QM) is a dynamic process. A Quality Management System is a structured model with a detailed representation of the organization and the processes in a certification body. It is very

important during the introduction of such a system that all employees understand the quality policy and try to realize it.

For the coordination of the diverse measures, the tasks and the works for the realization of a Quality Management System (QM), the designation of a Quality Management Agent (QMA) is necessary. He directly reports to the management of the certifier (cf. diagram 9).

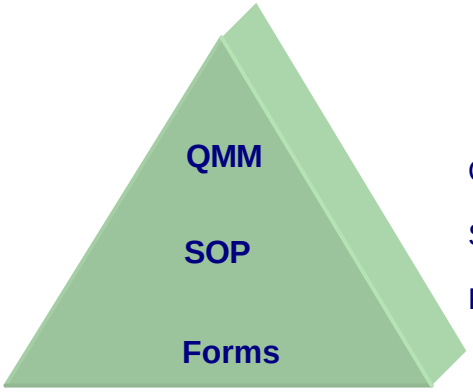
Within the framework of the QM the *Quality Policy* of an enterprise is of major importance. This *Quality Policy* shall be clear and comprehensible. It is formulated and passed by the management, giving a good example to the employees and is obligatory for the entire personnel of the certification body. A simple quality policy of a inspection body for organically produced foods describes the special features of the body in comparison to other suppliers, its aims (e.g. consumer-protection, efficiency in the daily courses, avoidance of mistakes) and the ways, how these defined objectives shall be achieved (e.g. optimization of the procedures, training). It is reasonable to formulate the objectives in such a way that they are measurable. The quality policy is regularly checked and updated if necessary.

3.3.2.5 Documentation in a Quality Management System

A Quality Management System is documented in writing and has always be up to date. Therefore a considerable expenditure of documentation arises, which is often considered a significant disadvantage of the introduction of such a system. This criticism may also be justified, because especially in the initial phase, the documentation is often too complicated and voluminous.

A reasonable documentation of the certification and the Quality Management System must however also be applicable in the daily practice of a certification body. On the one hand it should extensively describe the structure and processes, on the other hand however be preferably designed as simply as possible. The aim of a QM is to improve the dynamic quality, not to unnecessarily increase the bureaucratic expenditure.

Ideally, the documentation includes three levels, namely the Quality Management Manual, the Standard Operating Procedure (SOP) and the forms (cf. diagram 10).



QMM: Quality Management Manual

SOP: Standard Operating Procedure

Forms: e.g. contracts, scale of charges biodata, audit certificate

Diagram 10: Hierarchy of the documentation in a Quality Management System (QM)

The pyramid in diagram 10 represents the hierarchy of the documentation. From the higher level, one refers to the level which is below.

The most upper level of the pyramid represents the *Quality Management Manual*. Main purpose of the Quality Management Manual is to give a horizontal, concise and general description of the certification and QM System. The manual is published.

The subdivision of the manual in sections (chapters) follows to a large extent the requirements of the ISO 65 and the EN 45011, respectively (diagram 11). The manual can be set up in form of a loose-leaf volume which facilitates chapter wise supplements and alterations. It is advisable to use presentation formats with under-laid mask for each single chapter with the logo inside.

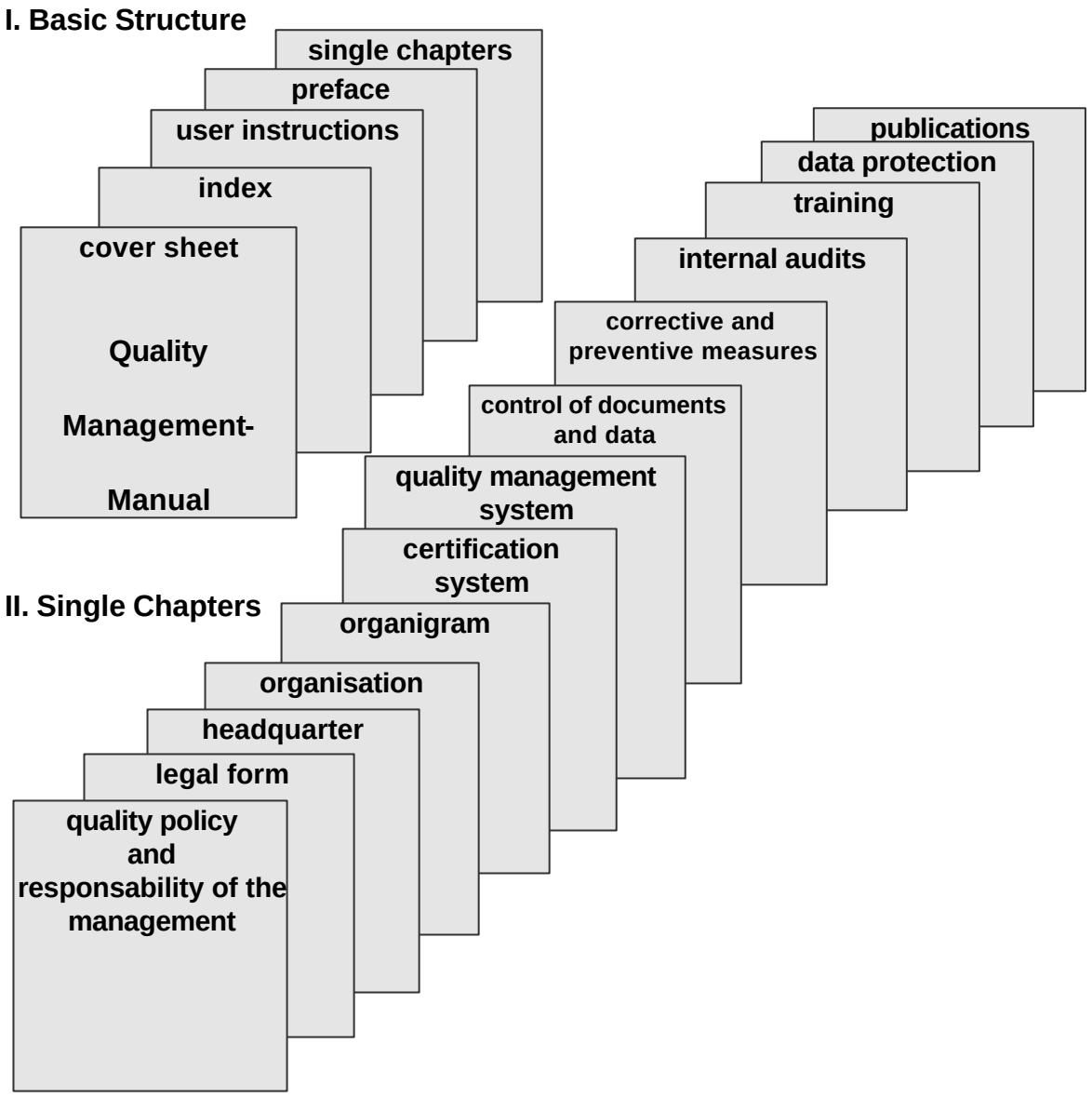


Diagram 11: Practicable structure and chapters of a Quality Management Manual

In published form the QM Manual usually comprises 20–40 pages. The single chapters refer to the Standard Operating Procedure (SOP).

These Standard Operating Procedures can also be summarized in a steward as leaf collection. In contrast to the single chapters of the Quality Management Manual the SOP of this *Procedure Manual* describe the individual courses in the certification body vertically and in detail (e.g. training and advanced training of the personnel, maintenance of confidentiality, planning and realization of inspections, evaluation, certification, treatment and evaluation of complaints). SOP are confidential and are never published.

Thus the SOP are associated with the Quality Management Manual and concretize its contents. There are no guidelines which SOP have to be drawn up. However they should be based according to the chapters of the Quality Management Manual. The numbering could be adopted from the manual. A pattern for the content structure of a SOP is shown in diagram 12.

The lowest level of the documentation comprises the forms (e.g. biodata, model contracts, model inspection reports, model certificates). These forms are part of a *form handbook* and are linked with the SOP. This is done by referring in the text of the SOP to these forms and by repeatedly mentioning those in the SOP designated forms as internal references under point 6 of the SOP (cf. diagram 12).

3.3.2.6 Control of documents in a Quality Management System

In a certification body there is a multitude of documents. They can be external documents (e.g. EC-Council Regulation on Organic Agriculture, ISO-Guide 65) or internal documents (e.g. SOP, forms).

Each document used must be unequivocally identifiable. Before its liberation it was tested and approved by authorized personnel. It is marked with its level of revision and should be available where it is required.

The most important principle is that in the certification body only approved documents are used and the application of outdated documents is excluded.

In order to fulfill the mentioned aims specific procedures must be defined in a certification body. They describe the creation, alteration, authorization, distribution and storage of documents.

name or logo	**Standard Operating Procedure (SOP) 2-5** ***Dealing with complaints***	page 1 of 2 Revision: 1 from: 6.2.1999
Date of preparation: 5 February 1999 signature:	Inspected and approved: 6 February 1999 signature:	
Date of issue: 6 February 1999		

title	subject	e.g. dealing with complaints
1. object		e.g. determine objective
2. scope	responsibility	*who is concerned by the instruction?* e.g.: management of the inspection body, office
3. terms	explain terms	*Which terms are important to this element?* e.g.: objection, complaint
4. responsibility	name or position	*Who is allowed to carry out the activity?* e.g.: office
5. implementation	work specification	How does *the activity has to be carried out*? e.g.: confirmation of receipt, procedure description, decision
6. references	list	Valid internal and external documents. e.g.: ISO/IEC-Guide 65 (extern), list of complaints (internal)
7. documentation		*How complaints are documented?* e.g.: book of complaints
8. modification service		reference to corresponding SOP (cf. chapter 3.4.2.6)
9. distribution list		indication of a distribution list

Diagram 12: Example for a Standard Operating Procedure (SOP)

In a *procedure for the creation, alteration and control of documents* it is laid down who is responsible for the elaboration and the alteration, respectively, the examination and the release of a document and how these works are carried out.

Each document (single chapters of the Quality Management Manual, SOP, form) must be provided with an unambiguous identification. Beside this identification the document contains the page numbering (page x of y) and the revision state. A possible document header of a SOP is shown in diagram 12, a possible footer of a form in diagram 13.

The distribution of the new or changed document can be generally determined in a distribution list or matrix of documents. Invalid and obsolete documents should be marked accordingly and kept over a certain period.

In a procedure for the *records system*, nature, scope and date of the certification body's records are defined and how they are archived systematically and confidentially. Documents should be easy to be found and like that enabled a *tracing-back* (e.g. check of former certification decisions). In this procedure, for instance, the contents and the safekeeping of a business-file of an inspected enterprise are defined.

Identification		Name	Date	Date of issue: 15/03/1999
08/15	preparation:	Claudia Leiter	07/03/1999	level of revision:
	release:	Klaus Prüfer	15/03/1999	revision: 0

Diagram 13: Example for a footer of a form

3.3.2.7 Procedures for the Quality Management Evaluation

The ISO-Guide 65 and EN 45011, respectively, designate the realization of internal audits and Quality Management Reviews.

Internal audits have the aim to prove the functionality and effectiveness of a QM-System elaborated by a certification body and implemented into practice. They are internally carried out in the enterprise and periodically check all areas of the certification body. They establish the actual state, uncover weak points and lead to measures for the elimination of these deficits *(correction-measures)*.

In the certification body, a SOP describes the planning and realization of internal audits like these. They are carried out annually following a fixed audit-plan. After the realization of the audit, the results are documented in a form. If mistakes were found, correction-measures are introduced whose effectiveness is checked again after a certain space of time. Requirements on the realization of internal audits are described in detail in the ISO-Guide 10011 from 1990.

Also the carrying out of *correction-measures* should be described in a SOP. Correction-measures in a well functioning system do not only become necessary on account of the results of internal audits but also, because mistakes are recognized and indicated by the employees of the certification body. Also complaints can lead to correction-measures, if they are justified.

The results of the internal audits become component of the Quality Management Reviews. A QM-Review is a critical contemplation of results (e.g. internal audits, carried out correction-measures). It is carried out by the management and is also documented. Also results of this evaluation can lead to alterations of the Quality Management System.

3.4 Establishment and Support of Local Inspection Bodies

The inspection and certification of organically grown products must be, in the long run, undertaken by local inspection bodies in developing countries. Only this way there can be a guarantee for a cheaper and long-term secure market access for small producers and their co-operatives to the important export markets of the EU and U.S.A.. Like this, new undesired dependence („bio-colonialism“) can be avoided. Initiatives to support local certification have recently been taken up by various organizations. Diagram 14 depicts a possible flow chart for the establishment of and the co-operation with local inspection bodies.

The main prerequisites for the proper functioning of locally and internationally operating inspection bodies are their independence and objectivity, the qualification of the inspection administration, of inspectors and certification staff, as well as the establishment and implementation of the inspection system. An inspection body is not permitted to carry out activities which could cause a conflict of interests and thereby, under certain conditions, could effect the neutral, objective execution of inspection and certification.

From experience, the description of guidelines and execution of inspection and certification with local inspection bodies are often already existing. These documents have usually been worked out following basic guidelines from the “International Federation of Organic Agriculture Movements“ (IFOAM), which have also entered the international legal requirements of the EU and U.S.A.

The documentation of the local inspection bodies and the evaluation of its previous activities are the basis for a gradually building up training and further education program, which is based on co-operation. An adaptation of the guidelines and of the standard control program to the requirements of the Codex Alimentarius (cf. chapter 2.3.) may be necessary.

An important task in building up local inspection bodies is the implementation of a quality management system equivalent to the ISO 65 or the EN 45011 (cf. chapter 3.4). In respect to the further education of the staff of a local inspection body, training in the area of agricultural production is not as often required as it is in the areas of processing, inspection and

certification of export enterprises and in the organization and documentation of the inspection body.

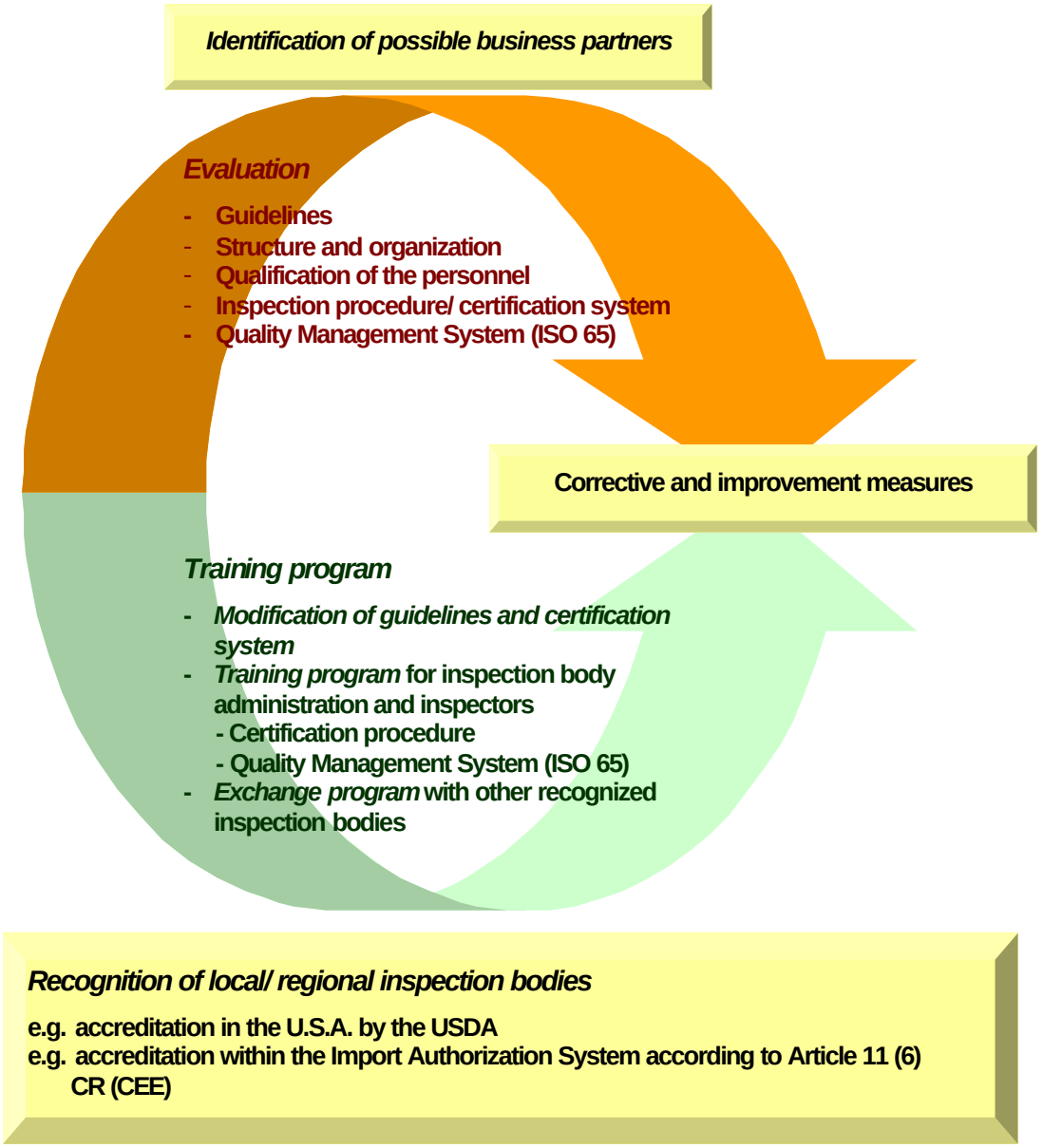


Diagram 14: Flow chart for the support of national inspection bodies

Regionally orientated exchange programs, which involve local inspection bodies certifying already for the international market, clearly have to be given preference in the implementation of training and further education.

4. Legislation on Organic Agriculture in Developing Countries

At present, many developing countries are trying to facilitate the access to target markets in industrialized countries by developing legal regulations for organic agriculture. Such legislation

procedures normally take a long time. The essential part is, that already the drafts take into account the legal regulations of the target markets in the EU, the U.S.A. and Japan and that the required equivalency (Codex Alimentarius, cf. chapter 2.3.) is met. For a high acceptance rate it is very important that the different interested parties (government representatives, producer, processors, exporters and consumer protection) in the developing countries are actively integrated in these procedures. Both, the government representatives and those involved in the market have to be aware that the objectives are a greater transparency in the market, a better consumer protection and especially an improvement in the framework conditions of international trade.

During the evaluation carried out by international expert groups, for instance, by EU representatives (cf. chapter 2.1.2.1.), what matters besides the required equivalency is the practical implementation of the regulations in the developing country. For this reason the establishment of national regulations in developing countries should be tied into a functional and internationally recognized local certification structure. This is how sufficient experience can be gained with the requirements of the import markets in the industrialized countries. This also prevents that by the end of a government agreement or the inclusion in the Third Country Register of the EU-Regulation on Organic Agriculture, only internationally recognized certification bodies would be active in the respective developing countries, whose activities would be established first (cf. chapter 2.1.2.2.) and create new dependence.

5. Local Certification in Developing Countries: Examples

Local, national inspection bodies in developing countries can independently take over the tasks of inspecting and certifying organically grown agricultural products. The following depicts some example cases. In the address appendix of this brochure, the names and addresses of several local inspection bodies in developing countries are listed.

Egypt

Till now there is no legal regulation on organic agriculture in Egypt.

The local certification bodies COAE and ECOA carry out nationwide inspections on organically run farms, processing units and exporters of organically produced foodstuffs. Both organisms prove their supervision by accreditation.

Argentina

In Argentina, the production of certified organically produced foodstuffs has already been officially controlled by several regulations since June of 1992. An application for member-ship in the third country register of the Council Regulation was made well in advance. Argentina was admitted onto the provisional third country register of the Council Regulation on Organic

Agriculture (CR (EEC) No. 3713/92) on the 1st of January, 1993. Thus, organic products from Argentina, accompanied by a product certificate (cf. diagram 3) from the Argentinean inspection bodies ARGENCERT and FAEA could be imported into the EU in a simplified procedure. In October 1994, the inspection body FAEA was taken off the provisional third country register, because, in the opinion of the EU-Commission, the equivalence of the inspections, which had been implemented by this inspection body, was no longer guaranteed.

While the naming of Argentina in the provisional third country register permitted that applications for an import authorization could be continued to be submitted and that consequently, other inspection bodies could be active in Argentina, this possibility of import will no longer exist after the admission of Argentina to the definite third country register by at 1st March 1997. Products from Argentina, which are registered by the Council Regulation on Organic Agriculture, can only be certified by ARGENCERT and OIA, if they are to be marketed as organic products in the EU.

Bolivia, Columbia, Peru and Nicaragua

In March 1998 some local Latin-American inspection bodies have formed a Latin-American certification company called BIOLATINA S.A.C.. BIOLATINA is mainly active in the four mentioned Latin-American countries where it runs regional offices.

Up to now in none of the four countries there is a legal regulation on Organic Agriculture. Organically produced foodstuffs are exported to the European Union by applying the import authorization procedure. However parliamentary initiatives have been taken in Bolivia, Columbia and Peru in order to establish an adequate regulation.

BIOLATINA S.A.C. was recognized in several EU-Member States via import authorization procedures according to Article 11 (6) of the CR (EEC). The supervision (cf. 3.1.4) is done by recognized experts.

The set up of BIOLATINA S.A.C. was promoted by the GTZ-project „Café Orgánico“.

Bolivia

In Bolivia, apart from BIOLATINA S.A.C., the local certification body BOLICERT is active. BOLICERT emerged as a subsidiary company from the Bolivian association of organic agriculture AOPEB.

BOLICERT is also recognized in the EU by import authorizations.

Brazil

Also Brazil was not accepted to the third country register of the CR (EEC) up to now. As local inspection body, the Instituto Biodinamico offers its services. The Instituto Biodinamico was

recognized in different EU-Member States as inspection body within the framework of several import authorization procedures.

China

In China, there is no legal regulation on Organic Agriculture up to now.

The Organic Food Development Center (OFDC) works as national inspection body. OFDC was founded in 1994 as department within the ministry of environment. The headquarter is in Nanjing. Moreover, OFDC has several branches in China. It was recognized in the EU in the framework of an import authorization procedure.

At present OFDC is also supported by a project of the GTZ.

Costa Rica

In Costa Rica legal regulations on organic agriculture have been passed. In November 2000 an on-the-spot examination have been carried out by EU experts in order to analyze the possibility of the inclusion in the Third Country Register (cf. chapter 2.1.2.1.). The preparation of the national regulation was supported by the GTZ.

Eco-LOGICA is the local inspection body that works in Costa Rica and at present, it is in process of being recognized by the EU.

Mexico

In Mexico there are also legal regulations on organic agriculture that are not yet equivalent to the Codex Alimentarius.

The evaluation of the local certification body CERTIMEX has been supported by the GTZ. At present, CERTIMEX also is in process of being recognized by the EU.

6. Prospects

The examples for individual developing countries, as presented in chapter 5, show that an international recognition of local inspection bodies is possible. National organizations, which have dealt with the cultivation methods of Organic Agriculture for many years, often have a large fund of experience. It is necessary to make this experience accessible for small-scale producers also by means of inspection and certification.

7. References

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IFOAM, 1998: BASIC STANDARDS OF ORGANIC AGRICULTURE AND FOOD PROCESSING. IFOAM HEAD OFFICE, ÖKOZENTRUM IMSBACH, D-66636 THOLEY – THOLEY, 10 US $.

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SCHMIDT, HANSPETER & MANON HACCIUS, 1998: EU-REGULATION „ORGANIC FARMING“. MARGRAF VERLAG, POSTFACH 1205, D-97985 WEIKERSHEIM.

VAUPEL, SUZANNE & KEN COMMINS, 1998: GUIDE TO REGULATORY REQUIREMENTS FOR EXPORTING ORGANIC FOODS INTO INTERNATIONAL MARKETS. IFOAM HEAD OFFICE, ÖKOZENTRUM IMSBACH, D-66636 THOLEY – THOLEY, 50 US $.

8. Additional information on the World Wide Web

http://www.fao.org
Web Site of the FAO with links to organic agriculture.

http://www.gtz.de
Web Site of the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GMBH Comment:At the date of printing this publication the GTZ intern Web Site on organic agriculture was in process (examples of projects, producers associations, certification, marketing)

http://www.gfrs.de
Web Site of the GfRS Gesellschaft für Ressourceschutz mbH (Society for the Protection of Ressources). Contains information on organic agriculture and certification of its products. Most of the information can be downloaded (i.e. Codex Alimentarius).

http://www.gfrs.de/em/progfrs.html
Web Site of the GTZ (temporary on the server of the GfRS) with information on the legal regulations of the EU and the U.S.A., ISO 65/ EN 45011, practical planning of inspections in developing countries including a download checklist and a list of national and international inspection bodies.

http://www.green-tradenet.de
Database for the marketing of organic products on the internet.

http://www.ifoam.org
Web Site of the IFOAM with a compilation of links.

http://www.iica.org
Web Site of the IICA with information on organic agriculture in Costa Rica and Central America.

9. Address appendix: list of national inspection bodies[2]

Egypt

Center of Organic Agriculture in Egypt (COAE)
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[2] The selection does not lay claim to completeness. It merely refers to those inspection bodies with whom positive working experience has already been collected.