

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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OUTCOME OF THE PHYSICAL WORKING GROUP ON ORGANIC AQUACULTURE

Discussion focused primarily on Annex 1, and in particular on the specific production rules for aquatic organisms. Most of the relevant definitions in section 2.2 were also discussed.

Most of the issues were cleared and a formulation acceptable for all participants was agreed for a number of paragraphs. In particular, the following issues were clarified following detailed discussions:

- The conditions for the use of non-organic juveniles in organic aquaculture (B2.9 and B2.10) were clarified. In the proposed text, paragraph B2.9 covers the use of wild animals and animals from non-organic farming for breeding purposes, when organic animals are not available. When non-organic animals are used for breeding purposes in accordance with these conditions, their offspring would be considered organic. Paragraph B2.10 determines the conditions for the use of non-organic juveniles for on-growing purposes. In this case, the juveniles brought into the production unit for on-growing purposes in accordance with these conditions would be considered organic. Conditions for the collection of wild seed for shellfish were also agreed.
- The general approach to be followed in relation to the sourcing of feed for organic aquaculture animals was agreed in sections B2.16 and B2.16a.
- The requirement to establish buffer zones between organic and non-organic production units was agreed (B2.7).
- There was an agreement on the approach to be followed in B2.8, only defining conversion periods for operations and not for stock – as this is covered under sections B2.9 and B2.10.

At the end of the discussion the main outstanding issues on which diverging opinions emerged and an agreement could not be reached were the following:

- The setting of **conversion periods (B2.8)**: while specific conversion periods will be determined by the relevant Competent Authorities, an agreement could not be reached on whether a minimum duration for these conversion periods should be defined in the Guidelines. Some Delegations considered that this issue should be left completely to the discretion of the Competent Authorities, while others argued that a common minimum duration would reassure all stakeholders that meaningful conversion periods are always applied to all types of organic aquaculture production. Another point for further discussion is whether such minimum period should be defined in terms of a fixed duration (e.g. 6 months) or of a production cycle. While some delegations preferred the latter option as in their view it would better adapt to the needs of different production types, others argued that the time needed to ensure that no residues of non-allowed substances remain in the soil or water is independent of the length of the production cycle and should determine the minimum duration of a conversion period in order for it to be meaningful.
- The use of **non-indigenous species (B2.9)**: some Delegations argued that non-indigenous species should only be used in organic aquaculture when they have already been present in the area without evidence of substantial negative impacts on biodiversity, in light of the serious threat of biodiversity represented by invasive alien species. Other delegations considered that this approach would be too restrictive and this issue should not be addressed in the Guidelines.
- The use of **wild juveniles for on-growing purposes (B2.10)**: most Delegations agreed that only juveniles from non-organic farming should be allowed for on-growing purposes when organic juveniles are not available. In their view, allowing the capture of wild juveniles for on-growing purposes would present a risk to the conservation of wild stocks and it would not be in line with the

principle of limiting the use of external inputs in organic production. However, others considered that the use of wild juveniles should also be permitted for this purpose.

- The setting of **maximum stocking densities (B2.12)**: some Delegations considered that stocking densities should in general be lower than those used in conventional aquaculture, in order to better differentiate the two types of production, while others considered this formulation too restrictive and suggested an alternative wording referring to the quality of the aquatic environment.
- The rules on **husbandry practices and closed recirculation systems (B2.14)**: some Delegations supported the original text, allowing Competent Authorities to decide whether closed recirculation systems should be allowed. Others suggested an alternative formulation, which would not refer to closed recirculation systems but would require all types of organic production systems to be based on natural conditions with only limited use of artificial light, heating/cooling and oxygen content control.
- The allowed **breeding techniques (B2.15)**: while there was a general agreement on most of the techniques permitted or prohibited in this paragraph, Delegations had diverging views on some of these. In particular, some Delegations considered that the use of hormones should be allowed to induce spawning in captivity, while others argued that this would be in contradiction with the general principles of organic farming. In these Delegations' view, the possibility to allow the use of non-organic juveniles provided in paragraph B2.10 already addresses this issue. Some Delegations wanted to prohibit all methods to artificially induce polyploidy, while others wanted to limit this prohibition to chemically induced polyploidy only. Finally, the need to clarify the scope of the prohibition of single sex strains emerged.
- The sources of **feed for carnivorous animals (B2.16a)**: Delegations expressed different views on the order of priority of two of the allowed sources.

**PROPOSED DRAFT REVISION OF THE GUIDELINES FOR THE PRODUCTION, PROCESSING,
LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS: ORGANIC AQUACULTURE**

(At Step 3)

FOREWORD

1. These guidelines have been prepared for the purpose of providing an agreed approach to the requirements which underpin production of, and the labelling and claims for, organically produced foods.
2. The aims of these guidelines are:
 - to protect consumers against deception and fraud in the market place and unsubstantiated product claims;
 - to protect producers of organic produce against misrepresentation of other food products as being organic;
 - to ensure that all stages of production, preparation, storage, transport and marketing are subject to inspection and comply with these guidelines;
 - to harmonize provisions for the production, certification, identification and labelling have organically grown produce;
 - to provide international guidelines for organic food control systems in order to facilitate recognition of national systems as equivalent for the purposes of imports; and
 - to maintain and enhance organic food production systems in each country so as to contribute to local and global preservation.
3. These guidelines are at this stage a first step into official international harmonization of the requirements for organic products in terms of production and marketing standards, inspection arrangements and labelling requirements. In this area the experience with the development of such requirements and their implementation is still very limited. Moreover, consumer perception on the organic production method may, in certain detailed but important provisions, differ from region to region in the world. Therefore, the following is recognized at this stage:
 - the guidelines are a useful instrument in assisting countries to develop national regimes regulating production, marketing and labelling of organic foods;
 - the guidelines need regular improvement and updating in order to take into account technical progress and the experience with their implementation;
 - the guidelines do not prejudice the implementation of more restrictive arrangements and more detailed rules by member countries in order to maintain consumer credibility and prevent fraudulent practices, and to apply such rules to products from other countries on the basis of equivalency to such more restrictive provisions.
4. These guidelines set out the principles of organic production at farm, **[preparation, and the elaboration,]**storage, transport, labelling and marketing stages, and provides an indication of accepted permitted inputs for soil fertilizing and conditioning, **[plant]**-pest and disease control and **[of the production systems and the substances to be used as]** food additives and processing aids. For labelling purposes, the use of terms inferring that organic production methods have been used are restricted to products derived from operators under the supervision of a certification body or authority.
5. Organic food production is one among the broad spectrum of methodologies which are supportive of the environment. Organic production systems are based on specific and precise standards of production which aim at achieving optimal **[agricultural, livestock and aquatic]** ~~agro and aquatic~~ ecosystems which are socially, ecologically and economically sustainable. Terms such as “biological” and “ecological” are also used in an effort to describe the organic system more clearly. Requirements for organically produced foods differ from those for other food products in that production procedures are an intrinsic part of the identification and labelling of, and claim for, such products.
6. “Organic” is a labelling term that denotes products that have been produced in accordance with organic production standards and certified by a duly **[constituted authorized]** certification body or authority. Organic food production is based on minimizing the use of external inputs, avoiding the

use of synthetic fertilizers and pesticides. Organic production practices cannot ensure that products are completely free of residues, due to general environmental pollution. However, methods are used to minimize pollution of air, soil and water. Organic food handlers, processors and retailers adhere to standards to maintain the integrity of organic food products. The primary goal of organic food production is to optimize the health and productivity of interdependent communities of soil or aquatic life, plants, animals and people.

7. Organic food production is a holistic **[production]** management system which promotes and enhances **[agricultural, livestock and aquatic]** ~~agro and aquatic~~ **[the health of the]** ecosystem **[health]**, including biodiversity, **[and]** biological cycles, ~~[and soil or water biological activity. It emphasizes the use of management practices in preference to the use]~~ **It gives priority to the use of certain management practices in preference over the incorporation]** of off-farm inputs, taking into account that regional conditions require locally adapted systems. This is accomplished by using, where possible, cultural, biological and mechanical methods, as opposed to using synthetic substances, to fulfil any specific function within the system. An organic production system is designed to:
- a) enhance biological diversity within the whole system;
 - b) **[increase improve] [the soil or water] biological activity [of the production ecosystems];**
 - c) maintain long-term soil fertility or quality of the aquatic environment;
 - d) recycle wastes of plant and animal origin in order to return nutrients to the **[land ecosystem]**, thus minimizing the use of non-renewable resources;
 - e) rely on **[the use of]** renewable resources in **[locally-organized]** food production systems **[and locally produced feeds];**
 - f) promote the healthy use of soil, water and air as well as minimize all forms of pollution thereto that may result from food production practices;
 - g) handle food products with emphasis on careful processing methods in order to maintain the **[organic integrity and vital intrinsic]** qualities of the **[organic]** product at all stages;
 - h) **conserve** natural ~~[agro and aquatic]~~ resources **[of the production medium];**
 - j) become established on any existing farm through a period of conversion, the appropriate length of which is determined by site-specific factors such as the history of the land or aquatic medium **[in question]**, and type of ~~[crops, livestock, or aquatic]~~ organism to be produced.
- [k] guarantee a safe product that does not affect public health]**
8. The concept of close contact between the consumer and the producer is a long established practice. Greater market demand, the increasing economic interests in production, and the increasing distance between producer and consumer has stimulated the introduction of external control and certification procedures.
9. An **[integral essential]** component of certification is the inspection of the organic management system. Procedures for operator certification are based primarily on a yearly description of the food production enterprise as prepared by the operator in cooperation with the inspection body. Likewise, at the processing level, standards are also developed against which the processing operations and plant conditions can be inspected and verified. Where the inspection process is undertaken by the certification body or authority, there must be clear separation of the inspection and certification function. In order to maintain their integrity, certification bodies or authorities which certify the procedures of the operator should be independent of economic interests with regard to the certification of operators.
10. Apart from a small portion of food commodities marketed directly from the farm to consumers, most products find their way to consumers via established trade channels. To minimize deceptive practices in the market place, specific measures are necessary to ensure that trade and processing enterprises can be audited effectively. Therefore, the regulation of a process, rather than a final product, demands responsible action by all involved parties.
11. Import requirements should be based on the principles of equivalency and transparency as set out in the *Principles for Food Import and Export Inspection and Certification*.¹ In accepting imports of organic products, countries would usually assess the inspection and certification procedures and the standards applied in the exporting country.

¹ CAC/GL 20-1995.

12. Recognizing that organic production systems continue to evolve and that organic principles and standards will continue to be developed under these guidelines, the Codex Committee on Food Labelling (CCFL) shall review these guidelines on a regular basis. The CCFL shall initiate this review process by inviting member governments and international organizations to make proposals to the CCFL regarding amendments to these guidelines prior to each CCFL meeting.

SECTION 1. SCOPE

- 1.1 These guidelines apply to the following products which carry, or are intended to carry, descriptive labelling referring to organic production methods:
- a) unprocessed plants and plant products, algae-**[and their products]**, livestock and livestock products, and aquaculture animal and aquaculture animal products to the extent that the principles of production and specific inspection rules for them are introduced in Annexes 1 and 3; and
 - b) processed agricultural crop, livestock and aquatic products² intended for human or animal consumption derived from (a) above.
- 1.2 A product will be regarded as bearing indications referring to organic production methods where, in the labelling or claims, including advertising material or commercial documents, the product, or its ingredients, is described by the terms “organic”, **[“biodynamic”]**, “biological”, “ecological”, or words of similar intent **[different from natural]** including diminutives which, in the country where the product is placed on the market, suggests to the purchaser that the product or its ingredients were obtained according to organic production methods.
- 1.3 Paragraph 1.2 does not apply where these terms clearly have no connection with the method of production.
- 1.4 These guidelines apply without prejudice to other Codex Alimentarius Commission (CAC) provisions governing the production, preparation, marketing, labelling and inspection of the products specified in paragraph 1.1.
- 1.5 All materials and/or the products produced from genetically engineered/modified organisms (GEO/GMO) are not compatible with the principles of organic production (either the growing, manufacturing, or processing) and therefore are not accepted under these guidelines.

SECTION 2. DESCRIPTION AND DEFINITIONS

2.1 Description

Foods should only be referred to as ~~organic production methods~~ if they come from an organic production system employing management practices which seek to nurture ecosystems which achieve sustainable productivity, and provide weed, pest and disease control through a diverse mix of mutually dependent life forms, recycling plant and animal residues, crop selection and rotation, water management, tillage and cultivation. Soil fertility is maintained and enhanced by a system which optimizes soil biological activity and the physical and mineral nature of the soil as the means to provide a balanced nutrient supply for plant and animal life as well as to conserve soil resources. Production should be sustainable with the recycling of plant nutrients as an essential part of the fertilizing strategy. Pest and disease management is attained by means of the encouragement of a balanced host/predator relationship, augmentation of beneficial insect populations, biological and cultural control and mechanical removal of pests and affected plant parts. The basis for organic husbandry of terrestrial or aquatic animals is the development of a harmonious relationship between their environment, flora and fauna, and respect for their characteristic physiological and behavioural needs. This is achieved by a combination of providing good quality organically grown feedstuffs, appropriate stocking rates, animal husbandry systems appropriate to behavioural needs, and animal management practices that minimize stress and seek to promote animal health and welfare, prevent disease and avoid the use of chemical **[allopathic]** veterinary drugs (including antibiotics).

2.2 Definitions

For the purpose of these guidelines: *(check codex code of fish & fisheries products: aquaculture, clean water)*

Algae means macroalgae and microalgae, including phytoplankton occurring both naturally and under cultivation in aquatic environments, both of marine water as well as fresh water

² Until lists of ingredients of non agricultural origin and processing aids permitted in the preparation of products of livestock origin are elaborated, competent authorities should develop their own lists.

Aquaculture means the farming of aquatic organisms involving intervention in the rearing process to enhance production and the individual or corporate ownership of the stock being cultivated.

Aquatic organisms include [all animals, algae and plants living in water, excluding / fish, shellfish (crustaceans and molluscs), echinoderms, aquatic plants and algae, but exclude] insects, mammals, reptiles, birds and amphibians.

(Aquaculture) production cycle means the lifespan of an aquatic organisms from the earliest life stage to harvesting.

Audit is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.³

Certification is the procedure by which official certification bodies, or officially recognized certification bodies, provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems and examination of finished products.⁴

Certification body means a body which is responsible for verifying that a product sold or labelled as “organic” is produced, processed, prepared handled, and imported according to these guidelines.

Clean water means water from any source where harmful microbiological contamination, substances and/or toxic plankton are not present in such quantities that may affect the safety of aquatic organisms and their products for human consumption.

[Closed recirculation system means a type of **enclosed** containment system, with very limited and managed barrier-connection to open waters, and systems to treat the effluent water to enable its **circulation for** reuse.]

~~**[Containment system Production unit]** means **[equipment for growing aquaculture animals or algae – the facilities for the production of aquatic organisms]** which minimises the risk of **[their]** dispersal **[of the aquatic organism concerned]** - examples are, cages (net pens), ponds and tanks, **[long-line and rafts holding suspended ropes with the organisms attached and net bags for shellfish.]**~~

Conversion period means the transition from conventional to organic farming within a given period of time, during which the guidelines concerning the organic production have been fully and continuously applied.

Competent authority means the official government agency having jurisdiction.

Food product/product of [agricultural agroforestry] or aquatic origin means any product or commodity, **live, [in primary production,]** raw or processed, that is marketed for human consumption (excluding water, salt and additives) or animal feed.

Genetically engineered/modified organisms. The following provisional definition is provided for genetically/modified organisms.⁵ Genetically engineered/modified organisms, and products thereof, are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Techniques of genetic engineering/modification include, but are not limited to: recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. Genetically engineered organisms will not include organisms resulting from techniques such as conjugation, transduction and hybridization.

Ingredient means any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product although possibly in a modified form.⁶

Inspection is the examination of food or systems for control of food, raw materials, processing, and distribution including in-process and finished product testing, in order to verify that they conform

³ CAC/GL 20-1995.

⁴ CAC/GL 20-1995.

⁵ In the absence of a definition of genetically engineered/modified organisms agreed by the Codex Alimentarius Commission, this definition has been developed in order to provide initial guidance for governments in the application of these guidelines. This definition is therefore to remain under review in the light of other considerations by the Commission and its Committees. In the interim, member countries may also apply national definitions.

⁶ *General Standard for the Labelling of Prepackaged Foods*, Section 4 – Labelling of Prepackaged Foods (CODEX STAN 1-1985).

to requirements.⁷ For organic food, inspection includes the examination of the production and processing system.

Labelling means any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.⁸

Livestock means any domestic or domesticated animal including bovine (including buffalo and bison), ovine, porcine, caprine, equine, poultry **[aquaculture]** and bees raised for food or in the production of food.⁹ The products of hunting or fishing of wild animals shall not be considered part of this definition.

Marketing means holding for sale or displaying for sale, offering for sale, selling, delivering or placing on the market in any other form.

Official accreditation is the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services. For organic production the competent authority may delegate the accreditation function to a private body.

Officially recognized inspection systems/officially recognized certification systems are systems which have been formally approved or recognized by a government agency having jurisdiction.¹⁰

Operator means any person who produces, prepares or imports, with a view to the subsequent marketing thereof, products as referred to in Section 1.1, or who markets such products.

Plant protection product means any substance intended for preventing, destroying, attracting, repelling, or controlling any pest or disease including unwanted species of plants or animals during the production, storage, transport, distribution and processing of food, agricultural commodities, or animal feeds.

Preparation means the operations of slaughtering, processing, preserving and packaging of food products ~~[and also alterations made to the labelling concerning the presentation of the organic production method.]~~

Production means the operations undertaken to supply food products in the state in which they occur on the farm **[from the primary production to the consumer] [or aquaculture crop centre]**, including initial packaging and labelling of the product.

Veterinary drug means any substance applied or administered to any food-producing animal, such as meat or milk-producing animals, poultry, fish **[crustaceans and molluscs]** or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviour.¹¹

SECTION 3. LABELLING AND CLAIMS

General provisions

- 3.1 Organic products should be labelled in accordance with the *General Standard for the Labelling of Prepackaged Foods*.¹²
- 3.2 The labelling and claims of a product specified in Section 1.1(a) may refer to organic production methods only where:
- such indications show clearly that they relate to a method of food production;
 - the product was produced in accordance with the requirements of Section 4 or imported under the requirements laid down in Section 7;
 - the product was produced or imported by an operator who is subject to the inspection measures laid down in Section 6, and

⁷ CAC/GL 20-1995.

⁸ CODEX STAN 1-1985.

⁹ Provisions for aquaculture will be elaborated at a future date.

¹⁰ CAC/GL 20-1995.

¹¹ *Codex Alimentarius Commission Procedural Manual, Definitions.*

¹² CODEX STAN 1-1985.

- d) the labelling refers to the name and/or code number of the officially recognized inspection or certification body to which the operator who has carried out the production or the most recent processing operation is subject.
- 3.3 The labelling and claims of a product specified in paragraph 1.1(b) may refer to organic production methods only where:
- a) such indication show clearly that they relate to a method of food production and are linked with the name of the food product in question, unless such indication is clearly given in the list of ingredients;
 - b) all the ingredients of agricultural origin of the product are, or are derived from, products obtained in accordance with the requirements of Section 4, or imported under the arrangements laid down in Section 7;
 - c) the product should not contain any ingredient of non-agricultural origin not listed in Annex 2, Table 3;
 - d) the same ingredients shall not be derived from an organic and non-organic origin;
 - e) the product or its ingredients have not been subjected during preparation to treatments involving the use of ionizing radiation or substances not listed in Annex 2, Table 4;
 - f) the product was prepared or imported by an operator subject to the regular inspection system as set out in Section 6 of these guidelines; and
 - g) the labelling refers to the name and/or the code number of the official or officially recognized certification body or authority to which the operator who has carried out the most recent preparation operation is subject.
- 3.4 By way of derogation from paragraph 3.3(b),
- certain ingredients of agricultural **[livestock or aquaculture]** origin not satisfying the requirement in that paragraph may be used, within the limit of maximum level of 5% m/m of the total ingredients excluding salt and water in the final product, in the preparation of products as referred to in paragraph 1.1(b);
 - ~~[where such ingredients of agricultural origin are not available, or in sufficient quantity, in accordance with the requirements of Section 4 of these guidelines;]~~
- 3.5 Pending further review of the guidelines, Member Countries can consider the following with regard to products referred to in paragraph 1.1(b) marketed in their territory:
- the development of specific labelling provisions for products containing less than 95% ingredients of agricultural **[livestock and aquacultural]** ingredients;
 - the calculation of the percentages in 3.4 (5%) and in 3.5 (95%) on the basis of the ingredients of agricultural origin (instead of all ingredients excluding only salt and water);
 - the marketing of product with in transition/conversion labelling containing more than one ingredient of agricultural **[livestock and aquacultural]** origin.
- 3.6 In developing labelling provisions from products containing less than 95% of organic ingredients in accordance with the paragraph above, member countries may consider the following elements in particular for products containing **[between]** 95% and 70% of organic ingredients:
- a) the product satisfies the requirements of paragraphs 3.3(c), (d) (e), (f) and (g);
 - b) the indications referring to organic production methods should only appear on the front panel as a reference to the approximate percentage of the total ingredients including additives but excluding salt and water;
 - c) the ingredients, appear in descending order (mass/mass) in the list of ingredients;
 - d) indications in the list of ingredients appear in the same colour and with an identical style and size of lettering as other indications in the list of ingredient.
- Labelling of products in transition/conversion to organic**
- 3.7 Products of farms in transition to organic production methods may only be labelled as “transition to organic” after 12 months of production using organic methods providing that:
- a) the requirements referred to in paragraphs 3.2 and 3.3 are fully satisfied;

- b) the indications referring to transition/conversion do not mislead the purchaser of the product regarding its difference from products obtained from farms and/or farm units which have fully completed the conversion period;
- c) such indication take the form of words, such as “product under conversion to organic farming”, or similar words or phrase accepted by the competent authority of the country where the product is marketed, and must appear in a colour, size and style of lettering which is not more prominent than the sales description of the product;
- d) foods composed of a single ingredient may be labelled as “transition to organic” on the principal display panel;
- e) the labelling refers to the name and/or the code number of the official or officially approved certification body or authority to which the operator who has carried out the most recent preparation is subject.

Labelling of non-retail containers

- 3.8 The labelling of non-retail containers of product specified in paragraph 1.1 should meet the requirements set out in Annex 3, paragraph 10.

SECTION 4. RULES OF PRODUCTION AND PREPARATION

- 4.1 Organic production methods require that for the production of products referred to in paragraph 1.1(a):
- a) at least the production requirements of Annex 1 should be satisfied;
 - b) in the case where (a) (above) is not effective, substances listed in Annex 2, Tables 1 and 2 or substances approved by individual countries that meet the criteria established in Section 5.1, may be used as plant protection products, fertilizers, soil conditioners, insofar as the corresponding use is not prohibited in general food production in the country concerned in accordance with the relevant national provisions.
- 4.2 Organic processing methods require that for the preparation of products referred to in paragraph 1.1(b):
- a) at least the processing requirements of Annex 1 should be satisfied;
 - b) substances listed in Annex 2, Tables 3 and 4 or substances approved by individual countries that meet the criteria established in Section 5.1 may be used as ingredients of non-agricultural origin or processing aids insofar as the corresponding use is not prohibited in the relevant national requirements concerning the preparation of food products and according to good manufacturing practice.
- 4.3 Organic products should be stored and transported according to the requirements of Annex 1.
- 4.4 By derogation of the provisions of paragraphs 4.1 (a) and 4.2 (a), the competent authority may, with regard to the provisions on livestock and aquaculture production at Annex 1, provide for more detailed rules as well as for derogations for implementation periods in order to permit gradual development of ~~[organic farming practices]~~ **the organic production systems**.

SECTION 5. REQUIREMENTS FOR INCLUSION OF SUBSTANCES IN ANNEX 2 AND CRITERIA FOR THE DEVELOPMENT OF LISTS OF SUBSTANCES BY COUNTRIES

- 5.1 At least the following criteria should be used for the purposes of amending the permitted substance lists referred to in Section 4. In using these criteria to evaluate new substances for use in organic production, countries should take into account all applicable statutory and regulatory provisions and make them available to other countries upon request.
- Any proposals for the inclusion in Annex 2 of new substances must meet the following general criteria:
- i) they are consistent with principles of organic production as outlined in these Guidelines;
 - ii) use of the substance is necessary/essential for its intended use;
 - iii) manufacture, use and disposal of the substance does not result in, or contribute to, harmful effects on the environment;
 - iv) they have the lowest negative impact on human or animal health and quality of life; and
 - v) approved alternatives are not available in sufficient quantity and/or quality.

The above criteria are intended to be evaluated as a whole in order to protect the integrity of organic production. In addition, the following criteria should be applied in the evaluation process:

- a) if they are used for fertilization, soil conditioning purposes:
- they are essential for obtaining or maintaining the fertility of the soil or to fulfil specific nutrition requirements of crops, or specific soil-conditioning and rotation purposes which cannot be satisfied by the practices included in Annex 1, or other products included in Table 2 of Annex 2; and
 - the ingredients will be of plant, animal, microbial, or mineral origin and may undergo the following processes: physical (e.g., mechanical, thermal), enzymatic, microbial (e.g., composting, fermentation); only when the above processes have been exhausted, chemical processes may be considered and only for the extraction of carriers and binders;¹³ and
 - their use does not have a harmful impact on the balance of the soil ecosystem or the physical characteristics of the soil, or water and air quality; and
 - their use may be restricted to specific conditions, specific regions or specific commodities;
- b) if they are used for the purpose of plant disease or pest and weed control:
- they should be essential for the control of a harmful organism or a particular disease for which other biological, physical, or plant breeding alternatives and/or effective management practices are not available; and
 - their use should take into account the potential harmful impact on the **[environment habitat]**, the ecology (in particular non-target organisms) and the health of consumers, livestock and bees; and
 - substances should be of plant, animal, microbial, or mineral origin and may undergo the following processes: physical (e.g. mechanical, thermal), enzymatic, microbial (e.g. composting, digestion);
 - however, if they are products used, in exceptional circumstances, in traps and dispensers such as pheromones, which are chemically synthesized they will be considered for addition to lists if the products are not available in sufficient quantities in their natural form, provided that the conditions for their use do not directly or indirectly result in the presence of residues of the product in the edible parts;
 - their use may be restricted to specific conditions, specific regions or specific commodities;
- c) if they are used as additives or processing aids in the preparation or preservation of the food :
- these substances are used only if it has been shown that, without having recourse to them, it is impossible to:
 - produce or preserve the food, in the case of additives, or
 - produce the food, in the case of processing aids
 in the absence of other available technology that satisfies these Guidelines;
 - these substances are found in nature and may have undergone mechanical/physical processes (e.g. extraction, precipitation), biological/enzymatic processes and microbial processes (e.g. fermentation),
 - or, if these substances mentioned above are not available from such methods and technologies in sufficient quantities, then those substances that have been chemically synthesized may be considered for inclusion in exceptional circumstances;
 - their use maintains the authenticity of the product;
 - the consumer will not be deceived concerning the nature, substance and quality of the food;
 - the additives and processing aids do not detract from the overall quality of the product;
- d) if they are used for the purpose of cleaning and disinfection of ponds, cages, buildings and installations used for aquaculture production **[on condition of]**:
- **[they are being]** essential for the control of a harmful organism or a particular disease for which other biological, physical, or breeding alternatives and/or effective management practices are not available; and

¹³ The use of chemical processes in the context of these Criteria is an interim measure and should be reviewed.

- their use **[takes would take]** into account the potential harmful impact on the environment, the **[ecology nature]** (in particular non-target organisms), **[aquatic]** organisms **[from aquaculture]** and the health of consumers; and
- substances are of plant, animal, microbial, or mineral origin and may undergo the following processes: physical (e.g. mechanical, thermal), enzymatic, microbial (e.g. composting, digestion);
- their use may be restricted to specific conditions, specific regions or specific commodities.

In the evaluation process of substances for inclusion on lists all stakeholders should have the opportunity to be involved.

- 5.2 Countries should develop or adopt a list of substances that meet the criteria outlined in Section 5.1. ~~**[If these substances mentioned above are not available from such methods and technologies in sufficient quantities, then those substances that have been chemically synthesized may be considered for inclusion in exceptional circumstances]**~~

SECTION 6. INSPECTION AND CERTIFICATION SYSTEMS¹⁴

[PARAGRAPHS 6.1-6.7 UNCHANGED AND NOT REPRODUCED HERE]

- 6.8 An organic operator **[has to must]** present an organic management plan to a certification body for verification during inspection. The plan must be updated annually.
- 6.9 Official or officially recognized inspection and/or certification bodies or authority should:
- a) give the competent authority or its designate, for audit purposes, access to their offices and facilities and, for random audit of its operators, access to the facilities of the operators, together with any information and assistance deemed necessary by the competent authority or its designate for the fulfilment of its obligations pursuant to these guidelines;
 - b) send to the competent authority or its designate each year a list of operators subject to inspection for the previous year and present to the said authority a concise annual report.
- 6.10 The designated authority and the official or officially recognized certification body or authority referred to in paragraph 6.2 should:
- a) ensure that, where an irregularity is found in the implementation of Sections 3 and 4, or of the measures referred to in Annex 3, the indications provided for in paragraph 1.2 referring to the organic production method are removed from the entire lot or production run affected by the irregularity concerned;
 - b) where a manifest infringement, or an infringement with prolonged effects is found, prohibit the operator concerned from marketing products with indications referring to the organic production method for a period to be agreed with the competent authority or its designate.
- 6.11 The requirements of the *Guidelines for the Exchange of Information between Countries on Rejections of Imported Food*¹⁵ should apply where the competent authority finds irregularities and/or infringements in the application of these guidelines.

SECTION 7. IMPORTS

[CHAPTER UNCHANGED AND NOT REPRODUCED HERE]

ANNEX 1

PRINCIPLES OF ORGANIC PRODUCTION

A1. PLANTS AND PLANT PRODUCTS

[PARAGRAPHS 1-8 UNCHANGED AND NOT REPRODUCED HERE]

9. The collection of edible plants and parts thereof, growing naturally in natural areas, forests and agricultural areas, close to the seashore or bordering other aquatic environments is considered an organic production method provided that:

¹⁴ The systems conducted by certification bodies may in some countries be equivalent to those systems conducted by inspection bodies. Therefore, the term "inspection and certification" has been used wherever these systems may be synonymous.

¹⁵ CAC/GL 25-1997.

- the products are from a clearly defined collection area that is subject to the inspection/certification measures set out in Section 6 of these guidelines;
- those areas have received no treatments with products other than those referred to in Annex 2 for a period of three years before the collection;
- the collection does not disturb the stability of the natural habitat or the maintenance of the species in the collection area;
- the products are from an operator managing the harvesting or gathering of the products, who is clearly identified and familiar with the collection area.

A2. AQUATIC PLANTS, ALGAE AND THEIR PRODUCTS

1. The operation and management of the production of organic algae, whether in containment systems or not, should be consistent with the principles of organic farming.
2. The biodiversity of the aquatic environment and the quality of the surrounding water should be maintained or enhanced.
3. Harvested algae can be sold as organically produced when these Guidelines have been complied with. The criteria for site selection of aquaculture animal units in Section B2 of these guidelines should be applied as appropriate to production units for aquatic plants and algae. The criteria for conversion of plant and plant products in these guidelines (Annex I.A, 1-4) should be applied as appropriate to aquatic plants and algae production units. If a competent authority agrees to a conversion period shorter than 12 months, it should be at least the length of a production cycle.
4. Both farming and collection of algae should be carried out in areas which meet the criteria of paragraph 4 and 6 of Section B2.
5. The collection of edible aquatic plants and algae and parts thereof, growing naturally in an aquatic environment is considered an organic production method provided that the four conditions of Annex 1.A. paragraph 9 are met.
6. To maintain good quality growing material, the collection in the wild should be done in a sustainable manner.
7. Farming should be carried out in a sustainable manner at all stages from collection of seeds in the wild to harvesting. The application of supplementary fertilizer, e.g. those listed in A2, Table 1, using natural organic compounds to the growing area should be restricted to pond cultivation. Ropes and other equipment used for growing aquatic plants and algae should be re-used or re-cycled where possible. Removal of bio-fouling organisms should be by physical means only.
8. The operator should maintain detailed and up-to-date records as set out in Annex 3, paragraphs 7–15, where the terms livestock should be taken to read aquatic plants and algae, where appropriate.
9. Substances referred to in Annex 2, Table 2D may be used when essential for the control of a harmful organism or a particular disease for which other biological, physical or plant breeding alternatives and/or effective management practices are not available.

B1. LIVESTOCK AND LIVESTOCK PRODUCTS

[CHAPTER UNCHANGED AND NOT REPRODUCED HERE]

B2. AQUACULTURE ANIMALS AND THEIR PRODUCTS

General principles

1. The operation and management of aquaculture production, whether in containment systems or not, should be consistent with the principles of organic production and the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003), Section 6 and 7 as appropriate.
2. The biodiversity of the aquatic environment and the quality of the surrounding water should be maintained.
3. The organic management plan referred to in section 6.8 should cover – as applicable – nutrient discharge, repair and surveillance of technical equipment, and water quality monitoring for early detection of potential contaminants including from unlikely events.
4. The relevant conditions listed for site selection in Section 6.1.1 of the *Code of practice for fish and fishery products* should apply. The production area should have characteristics which allow the production of products while minimizing negative environmental impacts on surrounding natural

ecosystems. Production facilities should be located in areas where the risk of contamination is minimized and where sources of pollution are unlikely and can be controlled or mitigated. The boundaries of the production unit should be clearly defined and marked appropriately.

5. The conditions listed for the growing water quality in Section 6.1.2 of the *Code of practice for fish and fishery products* should apply. Water used for aquaculture should meet the physiological requirements of the species and be of a quality suitable for the production of food which is safe for human consumption. Waste water from domestic or industrial sources should not be used.
6. Substances permitted for use as fertilizers and conditioners in the cultivation of aquaculture animals **[(fish, crustaceans, molluscs and echinoderms)]** are listed in Annex 2, Table 1B.
7. The certification body or competent authority must ensure at the outset that the location of the production unit is suitable by conducting an assessment of potential sources of contamination including substances unacceptable to organic production systems. Buffer zones between organic and non-organic production units should be established by the certification body or competent authority, to separate organic and non-organic production.

Conversion period for operations

8. **[8. The conversion period of the facility should in general be at least [one year/one production cycle]. In cases where the water has been drained and the facility cleaned and disinfected, a shorter period [of at least six months] may be determined by the certification body or competent authority. In the case of non-enclosed facilities in open waters, a shorter period [of three months] may apply provided that cages (net pens) have not been treated with prohibited antifoulants and there are no other sources of exposure to prohibited substances. During the conversion period the stock should not be subject to treatments or exposed to products which are not permitted for the production of organic foods.]**

Origin of stock

9. Breeds adapted to local conditions shall be chosen. Selection criteria should include the capacity of animals to adapt to local conditions and the farming system, their vitality and resistance to pests and diseases **[as well as their previous presence in the area]** without evidence of significant adverse effects on local habitat or native species. Breeding stock should come from organic production units. If these are not available, they should be submitted to organic management for at least three months prior to breeding. In cases where organic breeding stock is not available, the Competent Authority may authorize the use of wild caught parent stock, provided that they are kept under organic management before breeding and providing their capture is compatible with the sustainable management of the wild stock.
10. **[When organic juveniles are not available, the Competent Authority may prescribe conditions, a time limit and percentage for the introduction into organic farms of juveniles from non-organic hatcheries and nurseries [or from wild sources] for on-growing purposes, provided that the latter two thirds of their production cycle or 90% of their final biomass is under organic management and providing the stock is healthy.]** For bivalve shellfish, seed may be wild-harvested from outside of the production area, provided that such harvesting is permitted by the competent authority, that there is no significant damage to the environment and that records are kept to allow it be tracked back to the collection area.

Production rules for husbandry and breeding

11. The production unit should provide sufficient space for the animals' needs in terms of stocking density. The aquatic animals should be provided with water with a flow rate and temperature which meets to the physiological requirements of the species with sufficient oxygen and, in the case of filter feeding animals, other nutritional factors for their needs. The temperature and light conditions should be suitable for the species concerned in the particular geographic location of the production unit. Equipment should be kept clean by physical means. Substances for cleaning and disinfection

such as those specified in Annex 2, Table 2B may be used only to the extent that the cleanliness of the equipment cannot be maintained by physical means.

12. Maximum stocking density should be reflective of the natural behaviour of species and in keeping with good health and welfare **[and should be low enough to maintain the quality of the aquatic environment / and in general be lower than used in conventional farming]**. Competent authorities, or other recognised bodies may develop and publicise guide values for maximum densities for the species grown under their authority.
13. Containment systems, when used, including cages (net pens) should be designed, constructed, located and operated to suit the requirements of the species cultivated, with the purpose of minimizing escapes and other negative environmental impacts and to prevent the entry of predatory species.
14. **[14. The Competent Authority should decide whether or not to approve closed recirculation systems after a thorough examination and evaluation of the total environmental viability and compatibility with organic production. / 14. Production should be based on natural conditions, including water temperature, oxygen content and natural light. Indoor production systems that are constantly dependent on artificial light, oxygen content and temperature regulation shall only be allowed in hatcheries and nurseries. The Competent authority may authorise limited use of artificial light, oxygen content and temperature control in other production units, provided this is fully compatible with the needs and welfare of the species farmed.]**
15. Breeding should reflect the natural situation as closely as possible, in terms of ambient conditions, using appropriate strains for the type of farming in question. Manual sorting or selection, manual stripping of gametes and incubation of eggs is allowed. **[Chemically]** induced polyploidy, cloning, artificial hybridization and techniques using genetic engineering **[and use of single sex strains]** are prohibited. **[For species that cannot spawn naturally in captivity spawning may be induced using exogenous releasing hormones only if other methods are not available. Broodstock treated with releasing hormone shall lose organic status when slaughtered, the offspring will be organic if they have been raised according to this guideline. Genetically modified organisms (GMOs) and stock treated using hormones must not be used.]**

Nutrition

16. Operators should design a feeding plan that takes the following factors into account:
 - a) Feed contamination should be avoided in compliance with national regulations or as determined by internationally agreed standards and a precautionary approach should be taken to avoid disease transmission via feedstuffs;
 - b) The feedstuffs should meet the animal's nutritional requirements at the various stages of its development with feed naturally available in the farming environment and/or organic feeds **[or if not available, sustainable wild sources of feed]**;
 - c) Use of growth promoters and synthetic amino acids is not permitted.
- 16a. In addition to the general factors listed in clause 16, regarding feeds for carnivorous aquaculture animals:
 - a) they should be provided according to the following order of priority;
 - a.1) organic feed products of aquaculture origin.
 - a.2) fishmeal and fish oil and ingredients derived from organic aquaculture trimmings.

[a.3/a.4] fishmeal and fish oil derived from trimmings of fish caught for human consumption in sustainable fisheries.

[a.3/a.4] organic feed material of plant or animal origin.
 - a.5) feed products derived from whole fish caught in sustainable fisheries as determined by the competent authority.
 - b) **[the ration may include up to 60% of organic plant material]**;
 - c) dead animals from any aquaculture production system should not be used when their death was due to disease or unknown cause

17. If substances are used as feedstuffs, nutritional elements, feed additives or processing aids or in the preparation of feedstuffs for aquaculture animals, the competent authority shall establish a positive list of substances in compliance with the criteria of Section B1, para. 18.
18. Notwithstanding the above, where an operator can demonstrate to the satisfaction of the official or officially recognized inspection/certification body that feedstuffs satisfying the requirement outlined in paragraph 16 above are not available, as a result of, for example, unforeseen severe natural or man-made events or extreme weather conditions, the inspection/certification body may allow a restricted percentage of feedstuffs not produced according to these guidelines to be fed for a limited time, providing it does not contain genetically engineered/modified organisms or products thereof. The competent authority shall set both the maximum percentage of non-organic feed allowed and any conditions relating to this derogation.
19. For an implementation period to be set by competent authority aquaculture animals will maintain their organic status providing 80% of feed calculated on a dry matter basis, is from organic sources produced in compliance with these Guidelines.

Health care

20. Disease prevention in organic aquaculture should be based on guidelines and standards set by the OIE [**the Code of Practice for Fish and Fisheries products (CAC/RCP 52-2003), section 6.3.2**] and the principles and practices for health care of livestock (terrestrial animals) in these guidelines, specifically Annex I, **B**, paragraphs, 20, 21, 22 and 24] and on the following additional points:

Ensuring that the site selection and design of the production unit is optimal and that there is regular cleaning and disinfection of premises with permitted substances where appropriate.

Phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal for which the treatment is intended.

To control ectoparasites such as sealice, appropriate production methods (and cleaner fish if available) should be used where possible, rather than parasiticides. Parasite treatments **[may be used if no alternative permitted treatments exist and]** should be limited to twice per year, with the exception of compulsory control schemes.

The use of veterinary drugs should be limited to two courses of treatment per year, with the exception of vaccines and compulsory eradication schemes. **[Veterinary drugs and antibiotics must not be withheld if this will result in a breach of relevant fish welfare standards.]** If the specified limits are exceeded the aquaculture animals concerned should not be sold as organic.
21. Hormonal treatment **must** not be used **[except for breeding in accordance with paragraph 15.]**

Harvesting and Transport

22. Harvesting should be carried out with reference to the Code of Practice for Fish and Fishery Products (Section 6.3.4 of CAC/RCP 52-2003). Guidelines and standards set by the OIE may be the specific normative basis for transport. The provisions on holding and transport in aquaculture production and on harvesting and transport (7.3), relaying (7.4) and depuration (7.5) of bivalve molluscs of the Codex Code of Practice for Fish and Fishery Products (Sections 6.3.5, 6.3.6, 7.3 7.4 and 7.5 of CAC/RCP 52-2003) should also apply. Live aquatic animals should be transported in suitable containers with clean water, which meets their physiological needs in terms of temperature and dissolved oxygen. Before use, tanks should be thoroughly cleaned, disinfected and rinsed. Precautions should be taken to reduce stress during transport, in particular regarding the density.

Slaughter

23. Guidelines and standards set by the OIE may be the specific normative base. Live aquaculture animals should be handled in such a way as to avoid unnecessary stress. Slaughter techniques should render fish immediately unconscious and insensible to pain.

Inspection

24. The operator should maintain detailed and up-to-date records and meet the relevant requirements of Annex 3 for inspection purposes.

C. HANDLING, STORAGE, TRANSPORTATION, PROCESSING AND PACKAGING

[CHAPTER UNCHANGED AND NOT REPRODUCED HERE]

ANNEX 2

PERMITTED SUBSTANCES FOR THE PRODUCTION OF ORGANIC FOODS

PRECAUTIONS

1. Any substances used in an organic system for soil **[and aquatic environment]** fertilization and conditioning, pest and disease control, for the health of livestock and aquaculture animals and quality of the animal products, or for preparation, preservation and storage of the food product should comply with the relevant national regulations.
2. Conditions for use of certain substances contained in the following lists may be specified by the certification body or authority, e.g. volume, frequency of application, specific purpose, etc.
3. Where substances are required for primary production they should be used with care and with the knowledge that even permitted substances may be subject to misuse and may alter the **[production]** ecosystem **[of the soil or farm]**.
4. The following lists do not attempt to be all inclusive or exclusive, or a finite regulatory tool but rather provide advice to governments on internationally agreed inputs. A system of review criteria as detailed in Section 5 of these Guidelines for products to be considered by national governments should be the primary determinant for acceptability or rejection of substances.

TABLE 1A

SUBSTANCES FOR USE IN SOIL FERTILIZING AND CONDITIONING

[TABLE UNCHANGED AND NOT REPRODUCED HERE]

TABLE 1B

SUBSTANCES [AND ORGANISM] USED AS FERTILIZERS AND CONDITIONERS [OF AQUACULTURE PONDS IN THE PRODUCTION ENCLOSURES OF AQUATIC ORGANISMS]

Substances	Description; compositional requirements; conditions of use
1. Organic substances	
1.1 Organic fertilizer made from organic materials; compost of crop residues, straw, sawdust, bark, wood waste, and other agricultural by-products	If substances are not from organic sources, they need to be recognized by a certification body or competent authority. Inorganic substances added to provide plant nutrients such as phosphate rock shall be permitted substances.
1.2 Manure, only composted	If substances are not from organic sources, they need to be recognized by a certification body or competent authority
1.3 Green manure, fresh crop residues and residual material of organic nature used in the farm	If substances are not from organic sources, they need to be recognized by a certification body or competent authority
1.4 Leftover products from slaughterhouses and industries such as sugar factories, tapioca factories, and fish sauce factories	Synthetic substances shall not be added and they need to be recognized by a certification body or competent authority
1.5 <u>[Bacteria, moulds, and enzymes Bioremediation organisms]</u>	If substances are not from organic sources, they need to be recognized by a certification body or competent authority

Substances	Description; compositional requirements; conditions of use
2. Inorganic substances	
2.1 Phosphate rock	
2.2 Ground limestone (In calcite or dolomite form, it is prohibited to use baked dolomite)	
2.3 Calcium silicate	
2.4 Sodium silicate	
2.5 Magnesium sulfate	
2.6 Clay minerals such as smectite, aolinite, Chlorite, etc	
2.7 Perlite, zeolite, and bentonite	
2.8 Rock potash, mined, potassium salt with less than 60% chloride	
2.9 Calcium from seaweed	
2.10 Seashells	
2.11 Potassium sulphate produced by physical processes	
2.12 Rock salt	
2.13 [Oxygen]	

TABLE 2A
SUBSTANCES FOR PLANT PEST AND DISEASE CONTROL

[TABLE UNCHANGED AND NOT REPRODUCED HERE]

TABLE 2B
CLEANING AND DISINFECTION TREATMENTS FOR ORGANIC AQUACULTURE

Substance	Description; compositional requirements; conditions for use
I. Substances for cleaning and disinfection of equipment and facilities, in the absence of aquaculture animals	

Substance	Description; compositional requirements; conditions for use
Ozone	
Sodium chloride	
Sodium hypochloride	
Lime (CaO, calcium oxide)	
Caustic soda	
Alcohol	
Hydrogen peroxide	
Organic acids (acetic acid, lactic acid, citric acid)	
Humic acid	
Peroxyacetic acids	
Iodophores	
Copper sulphate:	
Potassium permanganate	
Peracetic and peroctanoic acids	
Tea seed cake made of natural camelia seed (use restricted to shrimp production)	
II. Limited list of substances for use in the presence of aquaculture animals	
Limestone (Calcium carbonate) for pH control	
Dolomite for pH correction (use restricted to shrimp production).	

[- Chlorhexidine**- Detergents****- Potassium bicarbonate****- Potassium hydroxide**

- **Potassium peroxymonosulphate sulphate**
- **Soaps**
- **Soap-based algicide**
- **Sodium bicarbonate (baking soda)**
- **Sodium borate**
- **Sodium carbonate (soda ash)**
- **Surfactants**
- **Thiosulfate**
- **Ultraviolet**
- **Vinegar- Wetting agents]**

TABLE 2C

SUBSTANCES FOR PEST AND DISEASE CONTROL FOR AQUACULTURE IN THE ABSENCE OF ANIMALS OR IN THE PRESENCE OF ANIMALS

Substance	Description; compositional requirements; conditions for use
1. Tea meal (AA)	
2. Rotenone (AA)	
3. Potassium permanganate (PA) – listed above	Only allowed in the hatching stage with an advice from fishery biologist or veterinarian
4. Hydrogen peroxide (PA) - listed above	Only allowed in the hatching stage with an advice from fishery biologist or veterinarian
5. Povidone iodine (PA)	Only allowed in the hatching stage with an advice from fishery biologist or veterinarian

TABLE 2D - TO BE DEVELOPED

Table 2D	
SUBSTANCE USED FOR THE PURPOSE OF AQUATIC PLANT DISEASE	
Substance	Description; compositional requirement; conditions of use
Lactic acid	
Citric acid	
Acetic acid	
Malic acid	

TABLE 3

INGREDIENTS OF NON-AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3 OF THESE GUIDELINES

[TABLE UNCHANGED AND NOT REPRODUCED HERE]

Table 4

**PROCESSING AIDS WHICH MAY BE USED FOR THE PREPARATION OF
PRODUCTS OF AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3
OF THESE GUIDELINES**

[TABLE UNCHANGED AND NOT REPRODUCED HERE]

ANNEX 3

**MINIMUM INSPECTION REQUIREMENTS AND PRECAUTIONARY MEASURES UNDER THE
INSPECTION OR CERTIFICATION SYSTEM**

1. Inspection measures are necessary across the whole of the food chain to verify product labelled according to Section 3 of these guidelines conforms to internationally agreed practices. The official or officially recognized certification body or authority and the competent authority should establish policies and procedures in accordance with these guidelines.
2. Access by the inspection body to all written and/or documentary records and to the establishment under the inspection scheme is essential. The operator under an inspection should also give access to the competent or designated authority and provide any necessary information for third party audit purposes.

A. PRODUCTION UNITS

3. Production according to these guidelines should take place in a unit where the land parcels, production areas, farm buildings and storage facilities for crop, livestock and aquaculture **[and algae]** sites are clearly separate from **[these of]** any other unit which does not produce according to these guidelines; preparation and/or packaging workshops may form part of the unit, where its activity is limited to preparation and packaging of its own agricultural produce.
4. When the inspection arrangements are first implemented, the operator and the official or officially recognized certification body or authority should draw up and sign a document which includes:
 - a) a full description of the unit and/or collection areas, showing the storage and production premises, land parcels, aquaculture **[and algae]** sites and, where applicable, premises where certain preparation and/or packaging operations take place;
 - b) and, in the case of collection of wild plants and wild algae, the guarantees given by third parties, if appropriate, which the producer can provide to ensure that the provisions of Annex 1, para 9 are satisfied;
 - c) all the practical measures to be taken at the level of the unit to ensure compliance with these guidelines;
 - d) the date of the last application on the land parcels, aquatic sites and/or collection areas concerned of products the use of which is not compatible with Section 4 of these guidelines;
 - e) an undertaking by the operator to carry out operations in accordance with Sections 3 and 4 and to accept, in event of infringements, implementation of the measures as referred to in Section 6, paragraph 9 of these guidelines.
5. Each year, before the date indicated by the certification body or authority, the operator should notify the official or officially recognized certification body or authority of its schedule of production of crop **[products and]** livestock **[and aquatic]**, giving a breakdown by land parcel/herd, flock **[or]** hive **[or aquatic areas and installations]**.
6. Written and/or documentary accounts should be kept which enable the official or officially recognized certification body or authority to trace the origin, nature and quantities of all raw materials bought, and the use of such materials; in addition, written and/or documentary accounts should be kept of the nature, quantities and consignees of all food products sold. Quantities sold directly to the final consumer should preferably be accounted for on a daily basis. When the unit itself processes food products, its accounts must contain the information required in B2, third dash point of this Annex.

7. All livestock should be identified individually or, in the case of small mammals or poultry, by herd or flock or in the case of bees by hive and in the case of aquaculture animals by lot. Written and/or documentary accounts should be kept to enable tracking of livestock and bee colonies or aquaculture animals within the system at all times and to provide adequate traceback for audit purpose. The operator should maintain detailed and up-to-date records of:
 - a) breeding and/or origins of livestock or aquaculture animals;
 - b) registration of any purchases;
 - c) the health plan to be used in the prevention and management of disease, injury and reproductive problems;
 - d) all treatments and medicines administered for any purpose, including quarantine periods and identification of treated animals or hives;
 - e) feed provided and the source of the feedstuffs;
 - f) stock movements within the unit and hive movements within designated forage areas as identified on maps;
 - g) transportation, slaughter and/or sales.
 - h) extraction, processing and storing of all bee products.
8. Storage, on the unit, of input substances, other than those whose use is with paragraph 4.1(b) of these guidelines is prohibited.
9. The official or officially recognized certification body or authority should ensure that a full physical inspection is undertaken, at least once a year, of the unit. Samples for testing of products not listed in these guidelines may be taken where their use is suspected. An inspection report should be drawn up after each visit. Additional occasional unannounced visits should also be undertaken according to need or at random.
10. The operator should give the certification body or authority, for inspection purposes, access to the storage and production premises and to the parcels of land or aquatic sites, as well as to the accounts and relevant supporting documents. The operator should also provide the inspection body with any information deemed necessary for the purposes of the inspection.
11. Products referred to in Section 1 of these guidelines which are not in their packaging for the end consumer should be transported in a manner which should prevent contamination or substitution of the content with substances or product not compatible with these guidelines and the following information, without prejudice to any other indications required by law:
 - the name and address of the person responsible for the production or preparation of the product;
 - the name of the product; and
 - that the product is of organic status.
12. Where an operator runs several production units in the same area (parallel cropping), units in the area producing ~~[crop, crop products or algae and their products]~~ **plant products and/or algae, those** not covered by Section 1 should also be subject to the inspection arrangements as regards the dash points of paragraph 4 and paragraphs 6 and 8 above. Plants of indistinguishable varieties as those produced at the unit referred to in paragraph 3 above should not be produced at these units:
 - If derogations are allowed by the competent authority, the authority must specify the types of production and circumstances for which derogations are granted and the supplementary inspection requirements, such as unannounced site visits; extra inspections during harvest; additional documentary requirements; assessment of an operation's ability to prevent co-mingling, etc., which are to be implemented.
 - Pending further review of these guidelines, member countries can accept parallel cropping of the same variety, even if it is not distinguishable, subject to adequate inspection measures being applied.
13. In organic livestock and aquaculture animal production, all livestock on one and the same production unit must be reared in accordance with the rules laid down in these Guidelines. However, livestock not reared in accordance with these Guidelines may be present on the organic holding provided that they are separated clearly from livestock produced in accordance with these

Guidelines. The competent authority can prescribe more restrictive measures, such as different species.

14. The competent authority may accept that animals reared in accordance with the provisions of these Guidelines may be grazed on common land, or reared in aquatic zones held in common, provided that:
 - a) this land has not been treated with products other than those allowed in accordance with Section 4.1 (a) and (b) of these Guidelines, for at least three years;
 - b) a clear segregation between the animals reared in accordance with the provisions of these Guidelines, and the other animals can be organized.
15. For livestock or aquatic animal production, the competent authority should ensure, without prejudice to the other provisions in this Annex, that the inspections related to all stages of production and preparation up to the sale to the consumer ensure, as far as technically possible, the traceability of products from the production unit through processing and any other preparation until final packaging and/or labelling.

B. PREPARATION AND PACKAGING UNITS

1. The producer and/or operator and should provide:
 - a full description of the unit, showing the facilities used for the preparation, packaging and storage of food products before and after the operations concerning them;
 - all the practical measures to be taken at the level of the unit to ensure compliance these guidelines.

This description and the measures concerned should be signed by the responsible person of the unit and the certification body.

The report should include an undertaking by the operator to perform the operations in such a way as to comply with Section 4 of these guidelines and to accept, in the event of infringements, the implementation of measures as referred to in paragraph 6.9 of these guidelines and be countersigned by both parties.
2. Written accounts should be kept enabling the certification body or authority to trace:
 - the origin, nature and quantities of food products as referred to in Section 1 of these guidelines which have been delivered to the unit;
 - the nature, quantities and consignees of products as referred to in Section 1 of these guidelines which have left the unit;
 - any other information such as the origin, nature and quantities of ingredients, additives and manufacturing aids delivered to the unit and the composition of processed products, that is required by the certification body or authority for the purposes of proper inspection of the operations.
3. Where products not referred to in Section 1 of these guidelines are also processed, packaged or stored in the unit concerned:
 - the unit should have separate areas within the premises for the storage of products as referred to in Section 1 of these guidelines, before and after the operations;
 - operations should be carried out continuously until the complete run has been dealt with, separated by place or time from similar operations performed on products not covered by Section 1 of these guidelines;
 - if such operations are not carried out frequently, they should be announced in advance, with a deadline agreed on with the certification body or authority;
 - every measure should be taken to ensure identification of lots and to avoid mixtures with products not obtained in accordance with the requirements of these guidelines.
4. The official or officially recognized certification body or authority should ensure that a full physical inspection, at least once a year, of the unit. Samples for testing of products not listed in these guidelines may be taken where their use is suspected. An inspection report must be drawn up after each visit countersigned by the person responsible for the unit inspected. Additional occasional unannounced visits should also be undertaken according to need or at random.

5. The operator should give the official or officially recognized certification body or authority or authority, for inspection purposes, access to the unit and to written accounts and relevant supporting documents. The operator should also provide the inspection body with any information necessary for the purposes of inspection.
6. The requirements in respect to the transport as laid down in paragraph A.10 of this Annex are applicable.
7. On receipt of a product referred to in Section 1 of these Guidelines, the operator shall check:
 - the closing of the packaging or contained where it is required;
 - the presence of the indications referred to in A.10 of this Annex. The result of this verification shall be explicitly mentioned in the accounts referred to in point B.2. When there is any doubt that the product cannot be verified according to the production system provided for in Section 6 of this Guidelines, it must be placed on the market without indication referring to the organic production method.

C. IMPORTS

Importing countries should establish appropriate inspection requirements for the inspection of importers and of imported organic products.

LIST OF MEMBER COUNTRIES AND OBSERVER ORGANIZATIONS**PHYSICAL WORKING GROUP ON THE REVISION OF THE GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS (ORGANIC AQUACULTURE)**

SATURDAY, 7 MAY 2016

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OBSERVERS

Int Federation of Organic Agriculture Movements (IFOAM)
International Food Additives Council (IFAC)