

Agricultural

Marketing

Service

Grading and Verification Division 13952 Denver West Parkway, Suite 350 Lakewood, CO 80401

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This document outlines the requirements of EC No 834/2007 and EC No 889/2008 that apply specifically to certification bodies accredited under the USDA ISO Guide 65 Program. As a result, some requirements will not be sequential. The Grading and Verification (GV) Division, being the competent authority, has delegated control tasks to certification bodies (control bodies) in accordance with EC No 834/2007, Title V Controls, Article 27 Control system, paragraph 5.

This document also includes key comments regarding differences between the EU regulations and the USDA National Organic Program regulations.

The requirements of EC No 834/2007 are denoted with black text. The requirements of EC No 889/2008 are denoted with blue text. The requirements of other EC regulations cited with EC No 834 and 889 are denoted with green text. The key comments are cited within an embedded table with a red header and red border.

EC No 834/2007

Title I – Aim, Scope and Definitions

Article 1 Aim and Scope

1. This Regulation provides the basis for the sustainable development of organic production while ensuring the effective functioning of the internal market, guaranteeing fair competition, ensuring consumer confidence and protecting consumer interests.

It establishes common objectives and principles to underpin the rules set out under this Regulation concerning:

(a) all stages of production, preparation and distribution of organic products and their control;

(b) the use of indications referring to organic production in labelling and advertising.

2. This Regulation shall apply to the following products originating from agriculture, including aquaculture, where such products are placed on the market or are intended to be placed on the market:

(a) live or unprocessed agricultural products;

(b) processed agricultural products for use as food;

(c) feed;

(d) vegetative propagating material and seeds for cultivation.

The products of hunting and fishing of wild animals shall not be considered as organic production. This Regulation shall also apply to yeasts used as food or feed.

Approved by



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Article 1 Aim and Scope

Key Comment 1

The EU further defines the scope into 6 product categories: (1) unprocessed plant products; (2) live or unprocessed livestock products; (3) aquaculture products; (4) processed agricultural products used for food; (5) feed; and (6) vegetative propagating material and seeds for cultivation.

3. This Regulation shall apply to any operator involved in activities, at any stage of production, preparation and distribution, relating to the products set out in paragraph 2.

However, mass catering operations shall not be subject to this Regulation. Member States may apply national rules or, in the absence thereof, private standards, on labelling and control of products originating from mass catering operations, in so far as the said rules comply with Community Law.

4. This Regulation shall apply without prejudice to other community provisions or national provisions, in conformity with Community law concerning products specified in this Article, such as provisions governing the production, preparation, marketing, labelling and control, including legislation on foodstuffs and animal nutrition.

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Article 2 Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) **'organic production**' means the use of the production method compliant with the rules established in this Regulation, at all stages of production, preparation and distribution;

(b) '**stages of production, preparation and distribution**' means any stage from and including the primary production of an organic product up to and including its storage, processing, transport, sale or supply to the final consumer, and where relevant labelling, advertising, import, export and subcontracting activities;

(c) '**organic**' means coming from or related to organic production;

(d) **'operator'** means the natural or legal persons responsible for ensuring that the requirements of this Regulation are met within the organic business under their control;

(e) '**plant production**' means production of agricultural crop products including harvesting of wild plant products for commercial purposes;

(f) 'livestock production' means the production of domestic or domesticated terrestrial animals (including insects);

(g) the definition of 'aquaculture' is that given in Council Regulation (EC) No 1198/2006 of 27 July 2006 on the



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Article 2 Definitions

European Fisheries Fund;

From EC No 1198/2006:

aquaculture': the rearing or cultivation of aquatic organisms using techniques designed to increase the production of the organisms in question beyond the natural capacity of the environment; the organisms remain the property of a natural or legal person throughout the rearing or culture stage, up to and including harvesting.

(h) **'conversion'** means the transition from non organic to organic farming within a given period of time, during which the provisions concerning the organic production have been applied;

(i) '**preparation**' means the operations of preserving and/or processing of organic products, including slaughter and cutting for livestock products, and also packaging, labelling and/or alterations made to the labelling concerning the organic production method;

(j) the definitions of '**food'**, '**feed'** and '**placing on the market**' are those given in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;

From EC No 178/2002 Article 2 Definition of 'food':

For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

(*a*) *feed*;

(b) live animals unless they are prepared for placing on the market for human consumption;

(c) plants prior to harvesting;

(d) medicinal products within the meaning of Council Directives 65/65/EEC (1) and 92/73/EEC (2);

(e) cosmetics within the meaning of Council Directive 76/768/EEC (3);

(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC (4);

(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;



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Article 2 Definitions

(h) residues and contaminants.

From EC No 178/2002 Article 3 Other Definitions:

4. 'feed' (or 'feedingstuff') means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals:

8. 'placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves.

(k) 'labelling' means any terms, words, particulars, trade marks, brand name, pictorial matter or symbol relating to and placed on any packaging, document, notice, label, board, ring or collar accompanying or referring to a product;

(1) the definition of 'pre-packaged foodstuff' is that given in Article 1(3)(b) of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs;

From Directive 2000/13/EC Article 1(b):

'pre-packaged foodstuff' shall mean any single item for presentation as such to the ultimate consumer and to mass caterers, consisting of a foodstuff and the packaging into which it was put before being offered for sale, whether such packaging encloses the foodstuff completely or only partially, but in any case in such a way that the contents cannot be altered without opening or changing the packaging.

(m) 'advertising' means any representation to the public, by any means other than a label, that is intended or is likely to influence and shape attitude, beliefs and behaviours in order to promote directly or indirectly the sale of organic products;

(n) 'competent authority' means the central authority of a Member State competent for the organisation of official controls in the field of organic production in accordance with the provisions set out under this Regulation, or any other authority on which that competence has been conferred to; it shall also include, where appropriate, the corresponding authority of a third country;

(o) 'control authority' means a public administrative organisation of a Member State to which the competent authority has conferred, in whole or in part, its competence for the inspection and certification in the field of organic production in accordance with the provisions set out under this Regulation; it shall also include, where appropriate, the corresponding authority of a third country or the corresponding authority operating in a third country;

(p) 'control body' means an independent private third party carrying out inspection and certification in the field of organic production in accordance with the provisions set out under this Regulation; it shall also include, where appropriate, the corresponding body of a third country or the corresponding body operating in a third country;

(q) 'mark of conformity' means the assertion of conformity to a particular set of standards or other normative documents in the form of a mark;



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(r) the definition of 'ingredients' is that given in Article 6(4) of Directive 2000/13/EC;

From Directive 2000/13/EC Article 6 (4):

'Ingredient' shall mean any substance, including additives, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form.

(s) the definition of '**plant protection products**' is that given in Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market;

From Directive 91/414/EEC Article 2 Definitions:

'plant protection products' active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:

1.1. protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;

1.2. influence the life processes of plants, other than as a nutrient, (e.g. growth regulators);

1.3. preserve plant products, in so far as such substances or products are not subject to special Council of Commission provisions on preservatives;

1.4. destroy undesired plants; or

1.5. destroy parts of plants, check or prevent undesired growth of Plants.

(t) the definition of '**Genetically modified organism** (**GMO**)' is that given in Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and which is not obtained through the techniques of genetic modifications listed in Annex I.B of that Directive;

From Directive 2001/18/EC Article 2 Definitions:

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

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

(b) the techniques listed in Annex IA, part 2, are not considered to result in genetic modification



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Article 2 Definitions

From Directive 2001/18/EC Annex 1 A, Part 1 and 2 TECHNIQUES REFERRED TO IN ARTICLE 2(2): PART 1

Techniques of genetic modification referred to in Article 2(2)(a) are inter alia:

(1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2

Techniques referred to in Article 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B:

(1) in vitro fertilisation,

(2) natural processes such as: conjugation, transduction, transformation,

(3) polyploidy induction.

From Directive 2001/18/EC Annex 1 B, TECHNIQUES REFERRED TO IN ARTICLE 3:

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

(u) '**produced from GMOs**' means derived in whole or in part from GMOs but not containing or consisting of GMOs;

(v) '**produced by GMOs**' means derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs;

(w) the definition of 'feed additives' is that given in Regulation (EC) No 1831/2003 of the European Parliament



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and of the Council of 22 September 2003 on additives for use in animal nutrition;

From EC No 1831/2003 Article 2 Definitions:

(2) (a) 'feed additives' means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the *functions mentioned in Article 5(3);*

From EC No 1831/2003 Article 5(3):

The feed additive shall:

(a) favourably affect the characteristics of feed,

(b) favourably affect the characteristics of animal products,

(c) favourably affect the colour of ornamental fish and birds,

(d) satisfy the nutritional needs of animals,

(e) favourably affect the environmental consequences of animal production,

(f) favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs, or

(g) have a coccidiostatic or histomonostatic effect.

(x) 'equivalent', in describing different systems or measures, means that they are capable of meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity;

(y) '**processing aid**' means any substance not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product;

(z) the definition of 'ionising radiation' is that given in Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation and as restricted by national regulations concerning food and food ingredients concerning foods and food ingredients treated with ionising radiation.

From Directive 96/29/Euratom Article 1 Definitions:

Ionizing Radiation: the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometer or less or a frequency of 3 x 1015 Hertz or more capable of producing ions directly or indirectly.

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EC 889/2008

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Article 2 Definitions

(aa) 'mass catering operations' means the preparation of organic products in restaurants, hospitals, canteens and other similar food business at the point of sale or delivery to the final consumer.

Article 2 Definitions:

In addition to the definitions laid down in Article 2 of Regulation (EC) No 834/2007, the following definitions shall apply for the purposes of this Regulation:

(a) '**non-organic**': means not coming from or not related to a production in accordance to Regulation (EC) No 834/2007 and this Regulation;

(b) 'veterinary medicinal products': means products as defined in Article 1(2) of Directive 2001/82/EC of the European Parliament and of the Council concerning the Community code relating to veterinary medicinal products

From Directive 2001/82/EC Article 1 Definitions:

2. Veterinary medicinal product: Any substance or combination of substances presented for treating or preventing disease in animals.

Any substance or combination of substances which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals is likewise considered a veterinary medicinal product.

(c) '**importer**': means the natural or legal person within the community who presents a consignment for release for free circulation into the Community, either in person, or through a representative;

(d) 'first consignee' means the natural or legal person to whom the imported consignment is delivered and who will receive it for further preparation and/or marketing;

(e) 'holding' means all the production units operated under a single management for the purpose of producing agricultural products;

(f) 'production unit' means all assets to be used for a production sector such as production premises, land parcels, pasturages, open air areas, livestock buildings, fish ponds, containment systems for seaweed or aquaculture animals, shore or seabed concessions, the premises for the storage of crops, crop products, seaweed products, animal products, raw materials and any other input relevant for this specific production

(g) 'hydroponic production' means the method of growing plants with their roots in a mineral nutrient solution only or in an inert medium, such as perlite, gravel or mineral wool to which a nutrient solution is added;

(h) 'veterinary treatment' means all courses of a curative or preventive treatment against one occurrence of a specific disease;

(i) 'in-conversion feedingstuffs' means feedingstuffs produced during the conversion period to organic



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production, with the exclusion of those harvested in the 12 months following the beginning of the conversion as referred to in Article 17(1)(a) of Regulation (EC) No 834/2007;

(j) '**closed recirculation aquaculture facility**' means a facility where aquaculture takes place within an enclosed environment on land or on a vessel involving the recirculation of water, and depending on permanent external energy input to stabilize the environment for the aquaculture animals;

(k) '**energy from renewable sources**' means renewable non-fossil energy sources: wind, solar, geothermal, wave, tidal, hydropower, landfill gas, sewage treatment plant gas and biogases;

(l) **'hatchery'** means a place of breeding, hatching and rearing through the early life stages of aquaculture animals, finfish and shellfish in particular;

(m) '**nursery'** means a place where an intermediate farming system, between the hatchery and grow-out stages is applied. The nursery stage is completed within the first third of the production cycle with the exception of species undergoing a smoltification process;

(n) '**pollution'** in the framework of aquaculture and seaweed production means the direct or indirect introduction into the aquatic environment of substances or energy as defined in Directive 2008/56/EC of the European Parliament and of the Council and in Directive 2000/60/EC of the European Parliament and of the Council, in the waters where they respectively apply;

From Directive 2008/56/EC Article 3 Definitions:

8. 'pollution' means the direct or indirect introduction into the marine environment, as a result of human activity, of substances or energy, including human-induced marine underwater noise, which results or is likely to result in deleterious effects such as harm to living resources and marine ecosystems, including loss of biodiversity, hazards to human health, the hindering of marine activities, including fishing, tourism and recreation and other legitimate uses of the sea, impairment of the quality for use of sea water and reduction of amenities or, in general, impairment of the sustainable use of marine goods and services;

From Directive 2000/60/EC Article 2 Definitions:

Pollution means the direct or indirect introduction, as a result of human activity, of substances or heat into the air, water or land which may be harmful to human health or the quality of aquatic ecosystems or terrestrial ecosystems directly depending on aquatic ecosystems, which result in damage to material property, or which impair or interfere with amenities and other legitimate uses of the environment.

(o) '**polyculture'** in the framework of aquaculture and seaweed production, means the rearing of two or more species usually from different trophic levels in the same culture unit;

(p) '**production cycle**' in the framework of aquaculture and seaweed production, means the lifespan of an aquaculture animal or seaweed from the earliest life stage to harvesting;



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Article 2 Definitions

(q) '**locally grown species**' in the framework of aquaculture and seaweed production, means those which are neither alien nor locally absent species under Council Regulation (EC) No 708/2007. Those species listed in Annex IV of Regulation (EC) No 708/2007 may be considered as locally grown species.

(r) '**stocking density**' in the framework of aquaculture, means the live weight of animals per cubic metre of water at any time during the grow-out phase and in the case of flatfish and shrimp the weight per square metre of surface.

EC No 834/2007

Title II – Objectives and Principles for Organic Production

Article 3 Objectives Article 4 Overall principles Article 5 Specific principles applicable to farming Article 6 Specific Principles applicable to Processing of Organic Food Article 7 Specific Principles applicable to Processing of Organic Feed

Key Comment 2

Title II Articles 3 through 7 are specific to the EU Community. The GV Division does not assess certification bodies against these requirements. As a result, these Articles are not included within this document. (Refer to EC No 834/2007, Article 33, paragraph 1.)

EC No 834/2007 Title III – Production Rules CHAPTER 1 – General Production Rules

Article 8 – General Requirements

Operators shall comply with the production rules set out in this Title and with the implementing rules as detained in EC No 889/2008.

EC No 834/2007 Title III – Production Rules CHAPTER 1 – General Production Rules

Article 9 – Prohibition on the use of GMOs

1. GMOs and products produced from or by GMOs shall not be used as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, seeds, vegetative propagating material, micro-organisms and animals in organic production.

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EC No 834/2007 **Title III – Production Rules CHAPTER 1 – General Production Rules**

Article 9 – Prohibition on the use of GMOs

2. For the purpose of the prohibition referred to in paragraph 1 concerning GMOs or products produced from GMOs for food and feed, operators may rely on the labels accompanying a product or any other accompanying document, affixed, or provided...

3. For the purpose of the prohibition referred to in paragraph 1, with regard to products not being food or feed, or products produced by GMOs, operators using such non-organic products purchased from third parties shall require the vendor to confirm that the products supplied have not been produced from or by GMOs.

EC 889/2008

Article 69 Vendor declaration:

For the purpose of the application of Article 9(3) of Regulation (EC) No 834/2007 the vendor declaration that products supplied have not been produced from or by GMOs may follow the model set out in Annex XIII to this Regulation.

Key Comment 3

EU & NOP regulations are basically the same. NOP §205.105 - GMOs are prohibited.

The Preamble to EC 834 recognizes the "adventitious and technically unavoidable presence of GMOs. It states, "The aim is to have the lowest possible presence of GMOs in organic products. The existing labeling thresholds represent ceilings which are exclusively linked to the adventitious and technically unavoidable presence of GMOs."

The EU Directive and Regulations cited within EC No 834/2007, Article 9, paragraph 2 are in reference to the allowance of GMOs. A maximum threshold for the presence of authorized GMOs is set at 0.9% for all products, organic and non-organic provided that the presence is adventitious or technically unavoidable. Unauthorized GMOs cannot be present at any levels. Food or feed with "material which contains, consists of or is produced from GMOs in a proportion no higher than 0.5 %" is allowed to be placed on the market without required labeling as long as it meets the maximum threshold requirement.

Important: The EU excludes veterinary medicinal products from the prohibition on GMOs. The NOP exclusion is limited to vaccines.

Important: If the certification body has allowed products within the tolerance limits, there must be verification that they are authorized by the Member State(s) that the product will be exported to and that the presence is adventitious or technically unavoidable.

Important: However, if it meets the requirements of the EU based on exemptions identified in EU 834 or 889 and those identified above they will not necessarily meet the NOP. The presence of GMO's in NOP certified operations and products does not necessarily mean the operation or product is in violation with the Final Rule. For more information refer to NOP policy memo PM 11-13. If the product has been certified to the NOP as not containing GMO's then it will meet the requirements of the EU.



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EC No 834/2007 **Title III – Production Rules CHAPTER 1 – General Production Rules**

Article 10 – Prohibition on the use of ionising radiation

The use of ionising radiation for the treatment of organic food or feed, or of raw materials used in organic food or feed is prohibited.

Key Comment 4

EU & NOP regulations are the same. NOP §205.105 – Ionizing radiation is prohibited.

EC No 834/2007 **Title III – Production Rules CHAPTER 2 – Farm Production**

Article 11 – General farm production rules

The entire agricultural holding shall be managed in compliance with the requirements applicable to organic production.

However, a holding may be split up into clearly separated units or aquaculture production sites which are not all managed under organic production. As regards animals, different species shall be involved. As regards aquaculture the same species may be involved, provided that there is adequate separation between the production sites. As regards plants, different varieties that can be easily differentiated shall be involved.

Where, in accordance with the second subparagraph, not all units of a holding are used for organic production, the operator shall keep the land, animals, and products used for, or produced by, the organic units separate from those used for, or produced by, the non-organic units and keep adequate records to show the separation.

Key Comment 5

NOP §205.201(a)(5) - Allows parallel production on any operation as long as there are management practices and physical barriers established to prevent commingling of organic and non-organic on a split operation and this must be described in the OSP.

The EU allows parallel production on the same production unit under certain conditions as long as strict separation and supporting records are maintained. Please refer to implementing rules of EC 889 Article 40 for additional guidance.

NOP standards do not apply to aquaculture.



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EC No 834/2007 **Title III – Production Rules CHAPTER 2 – Farm Production**

Article 12 – Plant production rules

1. In addition to the general farm production rules laid down in Article 11, the following rules shall apply to organic plant production:

(a) organic plant production shall use tillage and cultivation practices that maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil compaction and soil erosion;

(b) the fertility and biological activity of the soil shall be maintained and increased by multiannual crop rotation including legumes and other green manure crops, and by the application of livestock manure or organic material, both preferably composted, from organic production;

Key Comment 6

(a) Is the same as NOP §205.203(a)

(b) Is the same as NOP §205.203(b) except the NOP does not require the green manure crops or livestock manure to be from organic production. This is a key difference as NOP certified operations may have to change sources in order to meet the EU requirements.

(c) the use of biodynamic preparations is allowed;

Article 3 Soil management and fertilization:

1. Where the nutritional needs of plants cannot be met by measures provided for in Article 12(1)(a), (b) and (c) of Regulation (EC) No 834/2007, only fertilisers and soil conditioners referred to in Annex I to this Regulation may be used in organic production and only to the extent necessary. Operators shall keep documentary evidence of the need to use the product.

2. The total amount of livestock manure applied on the holding may not exceed 170 kg of nitrogen per year/hectare of agricultural area used. This limit shall only apply to the use of farmyard manure, dried farmyard manure and dehydrated poultry manure, composted animal excrements, including poultry manure, composted farmyard manure and liquid animal excrements.

3. Organic-production holdings may establish written cooperation agreements exclusively with other holdings and enterprises which comply with the organic production rules, with the intention of spreading surplus manure from organic production. The maximum limit as referred to in paragraph 2, shall be calculated on the basis of all of the organic-production units involved in such cooperation.

4. Appropriate preparations of micro-organisms may be used to improve the overall condition of the soil or the availability of nutrients in the soil or in the crops.

5. For compost activation appropriate plant-based preparations or preparations of micro-organisms may be used.

(d) in addition, fertilisers and soil conditioners may only be used if they have been authorised for use in organic production under Article 16;



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Article 12 – Plant production rules

(e) mineral nitrogen fertilisers shall not be used;

Key Comment 7

- (c) There is no direct reference to biodynamic preparations in the NOP standards (d) Addressed by NOP §205.203. Those allowed for the EU have to be in accordance with
- Annex I of EC 889
- (e) The non-allowance of mineral nitrogen fertilizers is a key difference as the NOP allows the use of Sodium nitrate (chilean nitrate) as long as the use is restricted to 20% of the total crop's nitrogen requirement (205.602 (g))

(f) all plant production techniques used shall prevent or minimise any contribution to the contamination of the environment;

(g) the prevention of damage caused by pests, diseases and weeds shall rely primarily on the protection by natural enemies, the choice of species and varieties, crop rotation, cultivation techniques and thermal processes;

EC 889/2008

Article 5 Pest, disease and weed management:

1. Where plants cannot be adequately protected from pests and diseases by measures provided for in Article 12 (1)(a), (b), (c) and (g) of Regulation (EC) No 834/2007, only products referred to in Annex II to this Regulation may be used in organic production. Operators shall keep documentary evidence of the need to use the product.

2. For products used in traps and dispensers, except pheromone dispensers, the traps and/or dispensers, shall prevent the substances from being released into the environment and prevent contact between the substances and the crops being cultivated. The traps shall be collected after use and disposed off safely.

(h) in the case of an established threat to a crop, plant protection products may only be used if they have been authorised for use in organic production under Article 16:

Key Comment 8

EU & NOP regulations are similar:

- (f) Addressed by NOP §205.203(c)
- (g) Addressed by NOP §205.206. NOP requires a hierarchy to be followed before allowing substances and synthetics allowed on the National List (NL). It is important to note what inputs are being used and if they conform to the requirements of the EU annexes which are the only allowed inputs.
- (h) Products used for the NOP have to be in compliance with the standards and those allowed on the NL. Products used for the EU have to be in compliance with the substances allowed in the annexes of EC 889 which is a closed list.

(i) for the production of products other than seed and vegetative propagating material only organically produced



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seed and propagating material shall be used. To this end, the mother plant in the case of seeds and the parent plant in the case of vegetative propagating material shall have been produced in accordance with the rules laid down in this Regulation for at least one generation, or, in the case of perennial crops, two growing seasons;

(i) products for cleaning and disinfection in plant production shall be used only if they have been authorised for use in organic production under Article 16.

2. The collection of wild plants and parts thereof, growing naturally in natural areas, forests and agricultural areas is considered an organic production method provided that:

(a) those areas have not, for a period of at least three years before the collection, received treatment with products other than those authorised for use in organic production under Article 16;

(b) the collection does not affect the stability of the natural habitat or the maintenance of the species in the collection area.

Key Comment 9

EU & NOP regulations are similar, except that:

- Seeds and planting stock (vegetative propagating material) are addressed by NOP §205.204. It i) is important to note that the NOP does not require a specific period of organic supervision by an ACA before the land is certified as organic as long as there have been no prohibited substances applied for 3 years prior to harvest; the land is organically managed with an approved OSP in place which should occur prior to planting; the operation inspected; and certification granted.
- Products for cleaning and disinfection in plant production have not been included in the i) annexes of EC 889. In the interim, the certification body can authorize cleaning products but only if they have verification that the products are allowed by the EU for that specific use.

2. (a) Same as NOP §205.207 except that the treatment with any products must be in accordance with the applicable standard.

2. (b) Same as NOP §205.207.

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Article 4 Prohibition of hydroponic production: Hydroponic production is prohibited.

Article 6 Specific rules on mushroom production:

For production of mushrooms, substrates may be used, if they are composed only of the following components:

(a) farmyard manure and animal excrements:

(i) either from holdings producing according to the organic production method:



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(ii) or referred to in Annex I, only when the product referred to in point (i) is not available; and when they do not exceed 25 % of the weight of total components of the substrate, excluding the covering material and any added water, before composting;

(b) products of agricultural origin, other than those referred to in point (a), from holdings producing according to organic production method;

(c) peat not chemically treated;

(d) wood, not treated with chemical products after felling;

(e) mineral products referred to in Annex I, water and soil.

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Article 13 – Production rules for seaweed

1. The collection of wild seaweeds and parts thereof, growing naturally in the sea, is considered as an organic production method provided that:

(a) the growing areas are of high ecological quality and are not unsuitable from a health point of view

Kev Comment 10

The EU Directives cited within the Regulation address the quality of different bodies of waters such as lakes, rivers, and coastal waters (2000/60/EC); the quality of shellfish waters (2006/113/EC); and waters which meet the requirements for areas where live bivalve mollusk may be collected for direct human consumption (Class A) or areas where live bivalve mollusk may be collected and only placed on the market after treatment in a purification center so as to meet requirements for safe human consumption (Class B).

The application of this requirement by a certification body must be determined based on national regulations specific to the country where the certification takes place. The certification body must be able to verify that the waters utilized are of high ecological quality and are safe for harvesting.

(b) the collection does not affect the long term stability of the natural habitat or the maintenance of the species in the collection area.

2. The farming of seaweeds shall take place in coastal areas with environmental and health characteristics at least



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equivalent to those outlined in paragraph 1 in order to be considered organic. In addition to this:

(a) sustainable practices shall be used in all stages of production, from collection of juvenile seaweed to harvesting;

(b) to ensure that a wide gene-pool is maintained, the collection of juvenile seaweed in the wild should take place on a regular basis to supplement indoor culture stock;

(c) fertilisers shall not be used except in indoor facilities and only if they have been authorised for use in organic production for this purpose under Article 16.

Key Comment 11

The NOP standards do not specifically address seaweed. Since Article 13 is specific to wild seaweeds, §205.207 (Wild-crop harvesting practice standard) applies.

Key Difference: EU is more prescriptive in requirements for seaweed.

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CHAPTER 1a Seaweed production

Article 6a Scope:

This Chapter lays down detailed production rules for the collection and farming of seaweed. It applies mutatis mutandis to the production of all multi-cellular marine algae or phytoplankton and micro-algae for further use as feed for aquaculture animals.

Article 6b Suitability of aquatic medium and sustainable management plan:

1. Operations shall be situated in locations that are not subject to contamination by products or substances not authorised for organic production, or pollutants that would compromise the organic nature of the products.

2. Organic and non-organic production units shall be separated adequately. Such separation measures shall be based on the natural situation, separate water distribution systems, distances, the tidal flow, the upstream and the downstream location of the organic production unit.

3. An environmental assessment proportionate to the production unit shall be required for all new operations applying for organic production and producing more than 20 tonnes of aquaculture products per year to ascertain the conditions of the production unit and its immediate environment and likely effects of its operation. The operator shall provide the environmental assessment to the certification body. The content of the environmental assessment shall be based on Annex IV to Council Directive 85/337/EEC. If the unit has already been subject to an equivalent assessment, then its use shall be permitted for this purpose.

Directive 85/337/EEC as amended by Directive 97/11/EC ANNEX IV INFORMATION REFERRED TO **IN ARTICLE 5(1):**

1. Description of the project, including in particular:



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- a description of the physical characteristics of the whole project and the land-use requirements during the construction and operational phases.

- a description of the main characteristics of the production processes, for instance, nature and quantity of the materials used,

- an estimate, by type and quantity, of expected residues and emissions (water, air and soil pollution, noise, vibration, light, heat, radiation, etc.) resulting from the operation of the proposed project.

2. An outline of the main alternatives studied by the developer and an indication of the main reasons for this choice, taking into account the environmental effects.

3. A description of the aspects of the environment likely to be significantly affected by the proposed project, including, in particular, population, fauna, flora, soil, water, air, climatic factors, material assets, including the architectural and archaeological heritage, landscape and the inter-relationship between the above factors.

4. A description of the proposed project on the environment resulting from:

- the existence of the project,

- the use of natural resources,

- the emission of pollutants, the creation of nuisances and the elimination of waste,

- and the description by the developer of the forecasting methods used to assess the effects on the environment.

This description should cover the direct effects and any indirect, secondary, cumulative, short, medium and long-term, permanent and temporary, positive and negative effects of the project.

5. A description of the measures envisaged to prevent, reduce and where possible offset any significant adverse effects on the environment.

6. A non-technical summary of the information provided under the above headings. An indication of any difficulties (technical deficiencies or lack of know-how) encountered by the developer in compiling the required information.

4. The operator shall provide a sustainable management plan proportionate to the production unit for aquaculture and seaweed harvesting.

The plan shall be updated annually and shall detail the environmental effects of the operation, the environmental monitoring to be undertaken, and list measures to be taken to minimise negative impacts on the surrounding aquatic and terrestrial environments, including, where applicable, nutrient discharge into the environment per production cycle or per annum. The plan shall record the surveillance and repair of technical equipment.

5. Aquaculture and seaweed business operators shall by preference use renewable energy sources and recycle materials and shall draw up as part of the sustainable management plan a waste reduction schedule to be put in



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place at the commencement of operations. Where possible, the use of residual heat shall be limited to energy from renewable sources.

6. For seaweed harvesting a once-off biomass estimate shall be undertaken at the outset.

Article 6c Sustainable harvesting of wild seaweed:

1. Documentary accounts shall be maintained in the unit or premises and shall enable the operator to identify and the certification body to verify that the harvesters have supplied only wild seaweed produced in accordance with Regulation (EC) No 834/2007.

2. Harvesting shall be carried out in such a way that the amounts harvested do not cause a significant impact on the state of the aquatic environment. Measures shall be taken to ensure that seaweed can regenerate, such as harvest technique, minimum sizes, ages, reproductive cycles or size of remaining seaweed.

3. If seaweed is harvested from a shared or common harvest area, documentary evidence shall be available that the total harvest complies with this Regulation.

4. With respect to Article 73b(2)(b) and (c), these records must provide evidence of sustainable management and of no long-term impact on the harvesting areas.

Article 6d Seaweed Cultivation:

1. Seaweed culture at sea shall only utilise nutrients naturally occurring in the environment, or from organic aquaculture animal production, preferably located nearby as part of a polyculture system.

2. In facilities on land where external nutrient sources are used the nutrient levels in the **effluent** water shall be verifiably the same, or lower, than the inflowing water. Only nutrients of plant or mineral origin and as listed in Annex I may be used.

3. Culture density or operational intensity shall be recorded and shall maintain the integrity of the aquatic environment by ensuring that the maximum quantity of seaweed which can be supported without negative effects on the environment is not exceeded.

4. Ropes and other equipment used for growing seaweed shall be re-used or recycled where possible.

Article 6e Antifouling measures and cleaning of production equipment and facilities:

1. Bio-fouling organisms shall be removed only by physical means or by hand and where appropriate returned to the sea at a distance from the farm.

2. Cleaning of equipment and facilities shall be carried out by physical or mechanical measures. Where this is not satisfactory only substances as listed in Annex VII, Section 2 may be used.



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Key Comment 12

Key difference: The EU is more prescriptive in detail and includes stocking densities; specific housing requirements; that feed is obtained primarily from the same holding or in cooperation with other EU organic farms in the same region; manure from factory farming is prohibited; parasiticides for dairy and slaughter stock is allowed along with therapeutic veterinary medicines and antibiotics, with certain restrictions and withdrawal periods is allowed.

Important: Because of key differences and specific requirements for EU livestock operations, certified livestock operations need to be thoroughly reviewed to each specific requirement.

1. In addition to the general farm production rules laid down in Article 11, the following rules shall apply to livestock production:

Article 7 Scope:

Chapter 2 lays down detailed production rules for the following species: bovine including bubalus and bison, equidae, porcine, ovine, caprine, poultry (species as mentioned in Annex III) and bees.

(a) with regard to the origin of the animals:

(i) organic livestock shall be born and raised on organic holdings;

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Preamble Paragraph (28):

Under certain circumstances, farmers may experience difficulty in securing supplies of organically reared livestock and organic feedingstuffs and therefore authorisation should be granted for a limited number of nonorganically produced farm input to be used in restricted quantities.

(ii) for breeding purposes, non-organically raised animals may be brought onto a holding under specific conditions. Such animals and their products may be deemed organic after compliance with the conversion period referred to in Article 17(1)(c);

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Article 9 Origin of non-organic animals:

1. Non-organic animals may be brought onto a holding for breeding purposes, only when organic animals are not available in sufficient number and subject to the conditions provided for in paragraphs 2 to 5 of this Article.

2. Non-organic young mammals, when a herd or flock is constituted for the first time, shall be reared in accordance with the organic production rules immediately after they are weaned. Moreover, the following restrictions shall apply at the date on which the animals enter the herd:

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(a) buffalo, calves and foals shall be less than six months old:

(b) lambs and kids shall be less than 60 days old;

(c) piglets shall weigh less than 35 kg.

3. Non-organic adult male and nulliparous female mammals (has not had offspring), for the renewal of a herd or flock, shall be reared subsequently in accordance with the organic production rules. Moreover, the number of female mammals is subject to the following restrictions per year:

(a) up to a maximum of 10 % of adult equine or bovine, including *bubalus* and bison species, livestock and 20 % of the adult porcine, ovine and caprine livestock, as female animals;

(b) for units with less than 10 equine or bovine animals, or with less than five porcine, ovine or caprine animals any renewal as mentioned above shall be limited to a maximum of one animal per year.

Key Comment 13

3.(b) will be reviewed in 2012 with a view to phase it out.

4. The percentages referred to in paragraph 3 may be increased up to 40 %, subject to prior authorisation by the certification body, in the following special cases:

(a) when a major extension to the farm is undertaken;

(b) when a breed is changed;

(c) when a new livestock specialisation is initiated;

(d) when breeds are in danger of being lost to farming; and in that case, animals of those breeds must not necessarily be nulliparous.

5. For the renovation of apiaries, 10 % per year of the queen bees and swarms may be replaced by non-organic queen bees and swarms in the organic production unit provided that the queen bees and swarms are placed in hives with combs or comb foundations coming from organic production units.

(iii) animals existing on the holding at the beginning of the conversion period and their products may be deemed organic after compliance with the conversion period referred to in Article 17(1)(c);

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Article 38 Livestock and livestock products; paragraph 2:

2. Where non-organic animals exist on a holding at the beginning of the conversion period, their products may be deemed organic if there is simultaneous conversion of the complete production unit, including livestock, pasturage and/or any land used for animal feed. The total combined conversion period for both existing animals and their offspring, pasturage and/or any land used for animal feed, may be reduced to 24 months, if the animals are mainly fed with products from the production unit.

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(b) with regard to husbandry practices and housing conditions:

(i) personnel keeping animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals;

(ii) husbandry practices, including stocking densities, and housing conditions shall ensure that the developmental, physiological and ethological needs of animals are met;

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Article 10 Rules pertaining to housing conditions:

- 1. Insulation, heating and ventilation of the building shall ensure that air circulation, dust level, temperature, relative air humidity and gas concentration, are kept within limits which are not harmful to the animals. The building shall permit plentiful natural ventilation and light to enter.
- 2. Housing for livestock shall not be mandatory in areas with appropriate climatic conditions to enable animals to live outdoors.
- 3. The stocking density in buildings shall provide for the comfort, the well being and the species-specific needs of the animals which, in particular, shall depend on the species, the breed and the age of the animals. It shall also take account of the behavioural needs of the animals, which depend in particular on the size of the group and the animals' sex. The density shall ensure the animals' welfare by providing them with sufficient space to stand naturally, lie down easily, turn round, groom themselves, assume all natural postures and make all natural movements such as stretching and wing flapping.
- 4. The minimum surface for indoor and outdoor areas, and other characteristics of housing for different species and categories of animals, are laid down in Annex III.

Article 11 Specific housing conditions and husbandry practices for mammals:

- 1 Livestock housing shall have smooth, but not slippery floors. At least half of the indoor surface area as specified in Annex III shall be solid, that is, not of slatted or of grid construction.
- 2 The housing shall be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product listed in Annex I.
- 3 The housing of calves in individual boxes shall be forbidden after the age of one week.
- 4 Sows shall be kept in groups, except in the last stages of pregnancy and during the suckling period.
- 5 Piglets shall not be kept on flat decks or in piglet cages.



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6 Exercise areas shall permit dunging and rooting by porcine animals. For the purposes of rooting different substrates can be used.

Article 12 Specific housing conditions and husbandry practices for poultry:

1. Poultry shall not be kept in cages.

2. Water fowl shall have access to a stream, pond, lake or a pool whenever the weather and hygienic conditions permit in order to respect their species-specific needs and animal welfare requirements.

3. Buildings for all poultry shall meet the following conditions:

(a) at least one third of the floor area shall be solid, that is, not of slatted or of grid construction, and covered with a litter material such as straw, wood shavings, sand or turf;

(b) in poultry houses for laying hens, a sufficiently large part of the floor area available to the hens shall be available for the collection of bird droppings;

(c) they shall have perches of a size and number commensurate with the size of the group and of the birds as laid down in Annex III.

(d) they shall have exit/entry pop-holes of a size adequate for the birds, and these pop-holes shall have a combined length of at least 4 m per 100 m2 area of the house available to the birds;

(e) each poultry house shall not contain more than:

(i) 4,800 chickens,

- (ii) 3,000 laying hens,
- (iii) 5,200 guinea fowl,

(iv) 4,000 female Muscovy or Peking ducks or 3,200 male Muscovy or Peking ducks or other ducks,

(v) 2,500 capons, geese or turkeys;

(f) the total usable area of poultry houses for meat production on any single unit, shall not exceed 1,600 m2;

(g) poultry houses shall be constructed in a manner allowing all birds easy access to open air area.

4. Natural light may be supplemented by artificial means to provide a maximum of 16 hours light per day with a continuous nocturnal rest period without artificial light of at least eight hours.



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5. To prevent the use of intensive rearing methods, poultry shall either be reared until they reach a minimum age or else shall come from slow-growing poultry strains. Where slow-growing poultry strains are not used by the operator the following minimum age at slaughter shall be:

(a) 81 days for chickens,

(b) 150 days for capons,

(c) 49 days for Peking ducks,

(d) 70 days for female Muscovy ducks,

(e) 84 days for male Muscovy ducks,

(f) 92 days for Mallard ducks,

(g) 94 days for guinea fowl,

(h) 140 days for male turkeys and roasting geese and

(i) 100 days for female turkeys.

The certification body shall define the criteria of slow-growing strains or draw up a list thereof and provide this information to operators.

Article 15 Stocking density:

1. The total stocking density shall be such as not to exceed the limit of 170 kg of nitrogen per year and hectare of agricultural area as referred to in Article 3(2).

Key Comment 14

170 kg (374.78 lbs) of nitrogen per year and hectare (2.47 acres)

2. To determine the appropriate density of livestock referred to above, the certification body shall set out the livestock units equivalent to the above limit, taking as a guideline, the figures laid down in Annex IV.

(iii) the livestock shall have permanent access to open air areas, preferably pasture, whenever weather conditions and the state of the ground allow this unless restrictions and obligations related to the protection of human and animal health are imposed on the basis of local community legislation;

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Article 14 Access to open air areas:

- 1. Open air areas may be partially covered.
- 2. Herbivores shall have access to pasturage for grazing whenever conditions allow.
- 3. In cases where herbivores have access to pasturage during the grazing period and where the winter-housing system gives freedom of movement to the animals, the obligation to provide open air areas during the winter months may be waived.
- 4. Notwithstanding paragraph 2, bulls over one year old shall have access to pasturage or an open air area.
- 5. Poultry shall have access to an open air area for at least one third of their life.
- 6. Open air areas for poultry shall be mainly covered with vegetation and be provided with protective facilities and permit fowl to have easy access to adequate numbers of drinking and feeding troughs.



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Where poultry are kept indoors due to restrictions or obligations imposed on the basis of Community legislation, they shall permanently have access to sufficient quantities of roughage and suitable material in order to meet their ethological needs.

Article 16 Prohibition of landless livestock production:

Landless livestock production, by which the operator of the livestock does not manage agricultural land and/or has not established a written cooperation agreement with another operator according to Article 3(3), is prohibited.

(iv) the number of livestock shall be limited with a view to minimising overgrazing, poaching of soil, erosion, or pollution caused by animals or by the spreading of their manure;

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Article 10 Rules pertaining to housing conditions, paragraph 4: 4. The minimum surface for indoor and outdoor areas, and other characteristics of housing for different species and categories of animals, are laid down in Annex III.

(v) organic livestock shall be kept separate from other livestock. However, grazing of common land by organic animals and of organic land by non-organic animals is permitted under certain restrictive conditions;

EC 889/2008

Article 17 Simultaneous production of organic and non-organic livestock:

1. Non organic livestock may be present on the holding provided they are reared on units where the buildings and parcels are separated clearly from the units producing in accordance with the organic production rules and a different species is involved.

2. Non-organic livestock may use organic pasturage for a limited period of time each year, provided that such animals come from a farming system as defined in paragraph 3(b) and that organic animals are not present at the same time on that pasture.

3. Organic animals may be grazed on common land, providing that:

(a) the land has not been treated with products not authorised for organic production for at least three years;...

(c) any livestock products from organic animals, whilst using this land, shall not be regarded as being from organic-production, unless adequate segregation from non-organic animals can be proved.

Key Comment 15

Operations that meet 3(a) do not qualify for NOP certification unless the NOP regulations are met.

4. During the period of transhumance animals may graze on non-organic land when they are being moved on foot from one grazing area to another. The uptake of non-organic feed, in the form of grass and other vegetation



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on which the animals graze, during this period shall not exceed 10 % of the total feed ration per year. This figure shall be calculated as a percentage of the dry matter of feedingstuffs from agricultural origin.

5. Operators shall keep documentary evidence of the use of provisions referred to in this Article.

(vi) tethering or isolation of livestock shall be prohibited, unless for individual animals for a limited period of time, and in so far as this is justified for safety, welfare or veterinary reasons;

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Article 39 Tethering of animals:

Where the conditions laid down in EC No 834/2007 Article 22(2)(a) apply, certification body may authorise cattle in small holdings to be tethered if it is not possible to keep the cattle in groups appropriate to their behaviour requirements, provided they have access to pastures during the grazing period according to Article 14(2), and at least twice a week access to open air areas when grazing is not possible.

Key Comment 16

Key difference: NOP §205.239(c)(2) states, "(c) The producer of an organic livestock operation may, in addition to the times permitted under §205.239(b), temporarily deny a ruminant animal pasture or outdoor access under the following conditions: (2) In the case of newborn dairy cattle for up to six months, after which they must be on pasture during the grazing season and may no longer be individually housed: *Provided*, That, an animal shall not be confined or tethered in a way that prevents the animal from lying down, standing up, fully extending its limbs, and moving about freely."

(vii) duration of transport of livestock shall be minimised;

(viii) any suffering, including mutilation, shall be kept to a minimum during the entire life of the animal, including at the time of slaughter;

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Article 18 Management of animals:

1. Operations such as attaching elastic bands to the tails of sheep, tail-docking, cutting of teeth, trimming of beaks and dehorning shall not be carried out routinely in organic farming. However, some of these operations may be authorised by the certification body for reasons of safety or if they are intended to improve the health, welfare or hygiene of the livestock on a case-by-case basis. Any suffering to the animals shall be reduced to a minimum by applying adequate anaesthesia and/or analgesia and by carrying out the operation only at the most appropriate age by qualified personnel.

2. Physical castration is allowed in order to maintain the quality of products and traditional production practices but only under the conditions set out in the second subparagraph of paragraph 1.

3. Mutilation such as clipping the wings of queen bees is prohibited.



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4. Loading and unloading of animals shall be carried out without the use of any type of electrical stimulation to coerce the animals. The use of allopathic tranquillisers, prior to or during transport, is prohibited.

(ix) apiaries shall be placed in areas which ensure nectar and pollen sources consisting essentially of organically produced crops or, as appropriate, of spontaneous vegetation or non-organically managed forests or crops that are only treated with low environmental impact methods. Apiaries shall be kept at sufficient distance from sources that may lead to the contamination of beekeeping products or to the poor health of the bees;

(x) hives and materials used in beekeeping shall be mainly made of natural materials;

(xi) the destruction of bees in the combs as a method associated with the harvesting of beekeeping products is prohibited;

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Article 8 Origin of organic animals, paragraph 2:

2. For bees, preference shall be given to the use of *Apis mellifera* and their local ecotypes.

Article 13 Specific requirements and housing conditions in beekeeping:

1. The siting of the apiaries shall be such that, within a radius of 3 km from the apiary site, nectar and pollen sources consist essentially of organically produced crops and/or spontaneous vegetation and/or crops treated with low environmental impact methods which cannot affect the qualification of beekeeping production as being organic. The above mentioned requirements do not apply where flowering is not taking place, or the hives are dormant

3. The hives shall be made basically of natural materials presenting no risk of contamination to the environment or the apiculture products.

4. The bees wax for new foundations shall come from organic production units.

5. Without prejudice to Article 25, only natural products such as propolis, wax and plant oils can be used in the hives.

6. The use of chemical synthetic repellents is prohibited during honey extractions operations.

7. The use of brood combs is prohibited for honey extraction.

Article 19 Feed from own holding or from other organic holdings, paragraphs 2 and 3:

2. In the case of bees, at the end of the production season hives shall be left with sufficient reserves of honey and pollen to survive the winter.

3. The feeding of bee colonies shall only be permitted where the survival of the hives is endangered due to climatic conditions and only between the last honey harvest and 15 days before the start of the next nectar or



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honeydew flow period. Feeding shall be with organic honey, organic sugar syrup, or organic sugar.

Article 25 Specific rules on disease prevention and veterinary treatment in beekeeping:

1. For the purposes of protecting frames, hives and combs, in particular from pests, only rodenticides (to be used only in traps), and appropriate products listed in Annex II, are permitted.

2. Physical treatments for disinfection of apiaries such as steam or direct flame are permitted.

3. The practice of destroying the male brood is permitted only to isolate the infestation of Varroa destructor.

4. If despite all preventive measures, the colonies become sick or infested, they shall be treated immediately and, if necessary, the colonies can be placed in isolation apiaries.

5. Veterinary medicinal products may be used in organic beekeeping in so far as the corresponding use is allowed by the EU for the specific purpose and in accordance with relevant national regulations.

6. Formic acid, lactic acid, acetic acid and oxalic acid as well as menthol, thymol, eucalyptol or camphor may be used in cases of infestation with *Varroa destructor*.

7. If a treatment is applied with chemically synthesised allopathic products, during such a period, the colonies treated shall be placed in isolation apiaries and all the wax shall be replaced with wax coming from organic beekeeping. Subsequently, the conversion period of one year laid down in Article 38(3) will apply to those colonies.

8. The requirements laid down in paragraph 7 shall not apply to products listed in paragraph 6.

Article 41 Management of beekeeping units for the purpose of pollination:

Where the conditions laid down in EC No 834/2007 Article 22(2)(a) apply, for the purpose of pollination actions an operator may run organic and non-organic beekeeping units on the same holding, provided that all the requirements of the organic production rules are fulfilled, with the exception of the provisions for the siting of the apiaries. In that case the product cannot be sold as organic. The operator shall keep documentary evidence of the use of this provision.

Article 44 Use of non-organic beeswax:

In the case of new installations or during the conversion period, non-organic beeswax may be used only

(a) where beeswax from organic beekeeping is not available on the market;

(b) where it is proven free of contamination by substances not authorised for organic production; and (c) provided that it comes from the cap.

(c) with regard to breeding:

(i) reproduction shall use natural methods. Artificial insemination is however allowed;



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(ii) reproduction shall not be induced by treatment with hormones or similar substances, unless as a form of veterinary therapeutic treatment in case of an individual animal;

(iii) other forms of artificial reproduction, such as cloning and embryo transfer, shall not be used;

Key Comment 17

Key Difference: In-vitro fertilization and embryo transfer is allowed by the NOP.

(iv) appropriate breeds shall be chosen. The choice of breeds shall also contribute to the prevention of any suffering and to avoiding the need for the mutilation of animals;

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Article 8 Origin of organic animals, paragraph 1:

1. In the choice of breeds or strains, account shall be taken of the capacity of animals to adapt to local conditions, their vitality and their resistance to disease. In addition, breeds or strains of animals shall be selected to avoid specific diseases or health problems associated with some breeds or strains used in intensive production, such as porcine stress syndrome, PSE Syndrome (pale-soft-exudative), sudden death, spontaneous abortion and difficult births requiring caesarean operations. Preference is to be given to indigenous breeds and strains.

(d) with regard to feed:

(i) primarily obtaining feed for livestock from the holding where the animals are kept or from other organic holdings in the same region;

(ii) livestock shall be fed with organic feed that meets the animal's nutritional requirements at the various stages of its development. A part of the ration may contain feed from holdings which are in conversion to organic farming;

EC 889/2008

Article 19 Feed from own holding or from other organic holdings, paragraph 1:

1. In the case of herbivores, except during the period each year when the animals are under transhumance subject to Article 17(4), at least 50 % of the feed shall come from the farm unit itself or in case this is not feasible, be produced in cooperation with other organic farms primarily in the same region.

Article 21 In-conversion feed:

1. Up to 30 % of the feed formula of rations on average may comprise in-conversion feedingstuffs. When the inconversion feedingstuffs come from a unit of the holding itself, this percentage may be increased to 100 %.

2. Up to 20 % of the total average amount of feedingstuffs fed to livestock may originate from the grazing or harvesting of permanent pastures, perennial forage parcels or protein crops, sown under organic management on lands in their first year of conversion, provided that they are part of the holding itself and have not been part of an organic production unit of that holding in the last five years. When both in-conversion feedingstuffs and

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feedingstuffs from parcels in their first year of conversion are being used, the total combined percentage of such feedingstuffs shall not exceed the maximum percentages fixed in paragraph 1.

3. The figures in paragraph 1 and 2 shall be calculated annually as a percentage of the dry matter of feedingstuffs of plant origin.

(iii) with the exception of bees, livestock shall have permanent access to pasture or roughage;

(iv) non organic feed materials from plant origin, feed materials from animal and mineral origin, feed additives, certain products used in animal nutrition and processing aids shall be used only if they have been authorised for use in organic production under Article 16;

EC 889/2008

Article 22 Products and substances referred to in EC No 834/2007 Article 14(1)(d)(iv): 1. Non-organic feed materials of plant and animal origin may be used in organic production subject to the restrictions laid down in Article 43 and only if they are listed in Annex V and the restrictions laid down therein are complied with.

2. Organic feed materials of animal origin, and feed materials of mineral origin may be used in organic production and only if they are listed in Annex V and the restrictions laid down therein are complied with.

3. Products and by-products from fisheries may be used in organic production only if they are listed in Annex V and the restrictions laid down therein are complied with.

4. Feed additives, certain products used in animal nutrition and processing aids may be used in organic production only if they are listed in Annex VI and the restrictions laid down therein are complied with.

Article 43 Use of non-organic feed of plant and animal origin for livestock:

Where the conditions laid down in EC No 834/2007 Article 22(2)(b) apply, the use of a limited proportion of non-organic feed of plant and animal origin is allowed where farmers are unable to obtain feed exclusively from organic production. The maximum percentage of non-organic feed authorised per period of 12 months for species other than herbivores shall be:

(a) 10 % during the period from 1 January 2009 to 31 December 2009;

(b) 5 % during the period from 1 January 2010 to 31 December 2011.

The figures shall be calculated annually as a percentage of the dry matter of feed from agricultural origin. The maximum percentage authorised of non-organic feed in the daily ration shall be 25 % calculated as a percentage of the dry matter.

The operator shall keep documentary evidence of the need for the use of this provision.



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(v) growth promoters and synthetic amino-acids shall not be used;

(vi) suckling mammals shall be fed with natural, preferably maternal, milk;

EC 889/2008

Article 20 Feed meeting animals' nutritional requirements:

1. All young mammals shall be fed on maternal milk in preference to natural milk, for a minimum period of three months for bovines including *bubalus* and bison species and equidae, 45 days for sheep and goats and 40 days for pigs.

2. Rearing systems for herbivores are to be based on maximum use of grazing pasturage according to the availability of pastures in the different periods of the year. At least 60 % of the dry matter in daily rations of herbivores shall consist of roughage, fresh or dried fodder, or silage. A reduction to 50 % for animals in dairy production for a maximum period of three months in early lactation is allowed.

3. Roughage, fresh or dried fodder, or silage shall be added to the daily ration for pigs and poultry.

4. The keeping of livestock in conditions, or on a diet, which may encourage anaemia, is prohibited.

5. Fattening practices shall be reversible at any stage of the rearing process. Force-feeding is forbidden.

(e) with regard to disease prevention and veterinary treatment:

(i) disease prevention shall be based on breed and strain selection, husbandry management practices, high quality feed and exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions;

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Article 23 Disease prevention, paragraph 4 and 5:

4. Housing, pens, equipment and utensils shall be properly cleaned and disinfected to prevent cross-infection and the build-up of disease carrying organisms. Faeces, urine and uneaten or spilt feed shall be removed as often as necessary to minimise smell and to avoid attracting insects or rodents.

5. Buildings shall be emptied of livestock between each batch of poultry reared. The buildings and fittings shall be cleaned and disinfected during this time. In addition, when the rearing of each batch of poultry has been completed, runs shall be left empty to allow vegetation to grow back. Member States shall establish the period for which runs must be empty. The operator shall keep documentary evidence of the application of this period. These requirements shall not apply where poultry is not reared in batches, is not kept in runs and is free to roam, throughout the day.

(ii) disease shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic



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veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined;

(iii) the use of immunological veterinary medicines is allowed;

Article 23 Disease prevention, paragraph 1 and 2:

1. The use of chemically synthesised allopathic veterinary medicinal products or antibiotics for preventive treatment is prohibited, without prejudice to Article 24(3).

2. The use of substances to promote growth or production (including antibiotics, coccidiostatics and other artificial aids for growth promotion purposes) and the use of hormones or similar substances to control reproduction or for other purposes (e.g. induction or synchronisation of oestrus), is prohibited.

Article 24 Veterinary treatment:

1. Where despite preventive measures to ensure animal health, animals become sick or injured they shall be treated immediately, if necessary in isolation and in suitable housing.

2. Phytotherapeutic, homoepathic products, trace elements and products listed in Annex V, part 3 and in Annex VI, part 1.1. shall be used in preference to chemically-synthesized allopathic veterinary treatment or antibiotics, provided that their therapeutic effect is effective for the species of animal, and the condition for which the treatment is intended.

3. If the use of measures referred to in paragraph 1 and 2 is not effective in combating illness or injury, and if treatment is essential to avoid suffering or distress of the animal, chemically-synthesised allopathic veterinary medicinal products or antibiotics may be used under the responsibility of a veterinarian.

4. With the exception of vaccinations, treatments for parasites and compulsory eradication schemes where an animal or group of animals receive more than three courses of treatments with chemically-synthesised allopathic veterinary medicinal products or antibiotics within 12 months, or more than one course of treatment if their productive lifecycle is less than one year, the livestock concerned, or produce derived from them, may not be sold as organic products, and the livestock shall undergo the conversion periods laid down in Article 38(1). Records of documented evidence of the occurrence of such circumstances shall be kept for the certification body.

5. The withdrawal period between the last administration of an allopathic veterinary medicinal product to an animal under normal conditions of use, and the production of organically produced foodstuffs from such animals, is to be twice the legal withdrawal period as referred to by national regulation(s) or, in a case in which this period is not specified, 48 hours.



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(iv) treatments related to the protection of human and animal health imposed on the basis of national regulation(s) shall be allowed;

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Article 23 Disease prevention, paragraph 3:

3. Where livestock is obtained from non-organic units, special measures such as screening tests or quarantine periods may apply, depending on local circumstances.

(f) with regard to cleaning and disinfection, products for cleaning and disinfection in livestock buildings and installations, shall be used only if they have been authorised for use in organic production under Article 16.

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Article 23 Disease prevention:

Only products listed in Annex VII may be used for cleaning and disinfection of livestock buildings installations and utensils. Rodenticides (to be used only in traps), and the products listed in Annex II, can be used for the elimination of insects and other pests in buildings and other installations where livestock is kept.

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Article 15 – Production rules for aquaculture animals

Key Comment 18

NOP standards do not apply to aquaculture. Aquaculture products cannot be certified under the NOP regulation.

1. In addition to the general farm production rules laid down in Article 11, the following rules shall apply to aquaculture animal production:

(a) with regard to the origin of the aquaculture animals:

(i) organic aquaculture shall be based on the rearing of young stock originating from organic broodstock and organic holdings;

(ii) when young stock from organic broodstock or holdings are not available, non-organically produced animals may be brought onto a holding under specific conditions;



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Article 1 Subject matter and scope, paragraph 2 (b):2. This Regulation shall not apply to: (b) to aquaculture animals other than those referred to in Article 25a.

(b) with regard to husbandry practices:

(i) personnel keeping animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals;

(ii) husbandry practices, including feeding, design of installations, stocking densities and water quality shall ensure that the developmental, physiological and behavioural needs of animals are met;

(iii) husbandry practices shall minimise negative environmental impact from the holding, including the escape of farmed stock;

(iv) organic animals shall be kept separate from other aquaculture animals;

(v) transport shall ensure that the welfare of animals is maintained;

(vi) any suffering of the animals including the time of slaughtering shall be kept to a minimum;

(c) with regard to breeding:

(i) artificial induction of polyploidy, artificial hybridisation, cloning and production of monosex strains, except by hand sorting, shall not be used;

(ii) the appropriate strains shall be chosen;

(iii) species-specific conditions for broodstock management, breeding and juvenile production shall be established;

(d) with regard to feed for fish and crustaceans:

(i) animals shall be fed with feed that meets the animal's nutritional requirements at the various stages of its development;

(ii) the plant fraction of feed shall originate from organic production and the feed fraction derived from aquatic animals shall originate from sustainable exploitation of fisheries;

(iii) in the case of non-organic feed materials from plant origin, feed materials from animal and mineral origin, feed additives, certain products used in animal nutrition and processing aids shall be used only if they have been authorised for use in organic production under Article 16;

(iv) growth promoters and synthetic amino-acids shall not be used;



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(e) with regard to bivalve molluscs and other species which are not fed by man but feed on natural plankton:

(i) such filter-feeding animals shall receive all their nutritional requirements from nature except in the case of juveniles reared in hatcheries and nurseries;

(ii) they shall be grown in waters which meet the criteria for areas where they may be collected for direct human consumption or after treatment in a purification center;

(iii) the growing areas shall be of high ecological;

Key Comment 19

The EU Directives cited within the Regulation address the quality of different bodies of waters such as lakes, rivers, and coastal waters (2000/60/EC); the quality of shellfish waters (2006/113/EC); and waters which meet the requirements for areas where live bivalve mollusk may be collected for direct human consumption (Class A) or areas where live bivalve mollusk may be collected and only placed on the market after treatment in a purification center so as to meet requirements for safe human consumption (Class B).

The application of this requirement by a certification body must be determined based on national regulations specific to the country where the certification takes place. The certification body must be able to verify that the waters utilized are of high ecological quality and are safe for harvesting.

(f) with regard to disease prevention and veterinary treatment:

(i) disease prevention shall be based on keeping the animals in optimal conditions by appropriate siting, optimal design of the holdings, the application of good husbandry and management practices, including regular cleaning and disinfection of premises, high quality feed, appropriate stocking density, and breed and strain selection;

(ii) disease shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined;

(iii) the use of immunological veterinary medicines is allowed;

(iv) treatments related to the protection of human and animal health imposed on the basis of national regulation(s) shall be allowed.



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(g) With regard to cleaning and disinfection, products for cleaning and disinfection in ponds, cages, buildings and installations, shall be used only if they have been authorised for use in organic production under Article 16.

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CHAPTER 2a Aquaculture animal production

Section 1 General rules

Article 25a Scope:

This Chapter lays down detailed production rules for species of fish, crustaceans, echinoderms and molluscs as covered by Annex XIIIa. It applies mutatis mutandis to zooplankton, micro-crustaceans, rotifers, worms and other aquatic feed animals.

Article 25b Suitability of aquatic medium and sustainable management plan:

1. The provisions of Article 6b(1) to (5) shall apply to this Chapter.

2. Defensive and preventive measures taken against predators under national rules shall be recorded in the sustainable management plan.

3. Verifiable coordination shall take place with the neighbouring operators in drawing up their management plans where applicable.

4. For aquaculture animal production in fishponds, tanks or raceways, farms shall be equipped with either natural-filter beds, settlement ponds, biological filters or mechanical filters to collect waste nutrients or use seaweeds and/or animals (bivalves and algae) which contribute to improving the quality of the effluent. Effluent monitoring shall be carried out at regular intervals where appropriate.

Article 25c Simultaneous production of organic and non-organic aquaculture animals:

1. The certification may permit hatcheries and nurseries to rear both organic and non-organic juveniles in the same holding provided there is clear physical separation between the units and a separate water distribution system exists.

2. In case of grow-out production, the certification body may permit organic and non-organic aquaculture animal production units on the same holding provided Article 6b(2) of this Regulation is complied with and where different production phases and different handling periods of the aquaculture animals are involved.

3. Operators shall keep documentary evidence of the use of provisions referred to in this Article.

Section 2 Origin of aquaculture animals

Article 25d Origin of organic aquaculture animals:

1. Locally grown species shall be used and breeding shall aim to give strains which are more adapted to farming conditions, good health and good utilisation of feed resources. Documentary evidence of their origin and



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treatment shall be provided for the certification body.

2. Species shall be chosen which can be farmed without causing significant damage to wild stocks.

Article 25e Origin and management of non-organic aquaculture animals:

1. For breeding purposes or for improving genetic stock and when organic aquaculture animals are not available, wild caught or non-organic aquaculture animals may be brought into a holding. Such animals shall be kept under organic management for at least three months before they may be used for breeding.

2. For on-growing purposes and when organic aquaculture juvenile animals are not available non-organic aquaculture juveniles may be brought into a holding. At least the latter two thirds of the duration of the production cycle shall be managed under organic management.

3. The maximum percentage of non-organic aquaculture juveniles introduced to the farm shall be: 80 % by 31 December 2011, 50 % by 31 December 2013 and 0 % by 31 December 2015.

4. For on-growing purposes the collection of wild aquaculture juveniles is specifically restricted to the following cases:

(a) natural influx of fish or crustacean larvae and juveniles when filling ponds, containment systems and enclosures:

(b) European glass eel, provided that an approved eel management plan is in place for the location and artificial reproduction of eel remains unsolved.

Section 3 Aquaculture Husbandry practices

Article 25f General aquaculture husbandry rules:

1. The husbandry environment of the aquaculture animals shall be designed in such a way that, in accordance with their species specific needs, the aquaculture animals shall:

(a) have sufficient space for their wellbeing:

(b) be kept in water of good quality with sufficient oxygen levels, and

(c) be kept in temperature and light conditions in accordance with the requirements of the species and having regard to the geographic location;

(d) in the case of freshwater fish the bottom type shall be as close as possible to natural conditions;

(e) in the case of carp the bottom shall be natural earth.

2. Stocking density is set out in Annex XIIIa by species or group of species. In considering the effects of stocking density on the welfare of farmed fish, the condition of the fish (such as fin damage, other injuries, growth rate, behaviour expressed and overall health) and the water quality shall be monitored.

3. The design and construction of aquatic containment systems shall provide flow rates and physiochemical



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parameters that safeguard the animals' health and welfare and provide for their behavioural needs.

4. Containment systems shall be designed, located and operated to minimize the risk of escape incidents.

5. If fish or crustaceans escape, appropriate action must be taken to reduce the impact on the local ecosystem, including recapture, where appropriate. Documentary evidence shall be maintained.

Article 25g Specific rules for aquatic containment systems:

1. Closed recirculation aquaculture animal production facilities are prohibited, with the exception of hatcheries and nurseries or for the production of species used for organic feed organisms.

2. Rearing units on land shall meet the following conditions:

(a) for flow-through systems it shall be possible to monitor and control the flow rate and water quality of both in-flowing and out-flowing water;

(b) at least five percent of the perimeter ("land-water interface") area shall have natural vegetation.

3. Containment systems at sea shall:

(a) be located where water flow, depth and water-body exchange rates are adequate to minimize the impact on the seabed and the surrounding water body;

(b) shall have suitable cage design, construction and maintenance with regard to their exposure to the operating environment.

4. Artificial heating or cooling of water shall only be permitted in hatcheries and nurseries. Natural borehole water may be used to heat or cool water at all stages of production.

Article 25h Management of aquaculture animals:

1. Handling of aquaculture animals shall be minimised, undertaken with the greatest care and proper equipment and protocols used to avoid stress and physical damage associated with handling procedures. Broodstock shall be handled in a manner to minimize physical damage and stress and under anaesthesia where appropriate. Grading operations shall be kept to a minimum and as required to ensure fish welfare.

2. The following restrictions shall apply to the use of artificial light:

(a) for prolonging natural day-length it shall not exceed a maximum that respects the ethological needs, geographical conditions and general health of farmed animals, this maximum shall not exceed 16 hours per day, except for reproductive purposes;

(b) abrupt changes in light intensity shall be avoided at the changeover time by the use of dimmable lights or background lighting.

3. Aeration is permitted to ensure animal welfare and health, under the condition that mechanical aerators are preferably powered by renewable energy sources



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All such use is to be recorded in the aquaculture production record.

4. The use of oxygen is only permitted for uses linked to animal health requirements and critical periods of production or transport, in the following cases:

(a) exceptional cases of temperature rise or drop in atmospheric pressure or accidental pollution,

- (b) occasional stock management procedures such as sampling and sorting,
- (c) in order to assure the survival of the farm stock.

Documentary evidence shall be maintained.

5. Slaughter techniques shall render fish immediately unconscious and insensible to pain. Differences in harvesting sizes, species, and production sites must be taken into account when considering optimal slaughtering methods.

Section 4 Breeding

Article 25i Prohibition of hormones: The use of hormones and hormone derivates is prohibited.

Section 5 Feed for fish, crustaceans and echinoderms

Article 25j General rules on feeds:

Feeding regimes shall be designed with the following priorities:

(a) animal health;

(b) high product quality, including the nutritional composition which shall ensure high quality of the final edible product:

(c) low environmental impact.

Article 25k Specific rules on feeds for carnivorous aquaculture animals:

1. Feed for carnivorous aquaculture animals shall be sourced with the following priorities:

(a) organic feed products of aquaculture origin;

(b) fish meal and fish oil from organic aquaculture trimmings;

(c) fish meal and fish oil and ingredients of fish origin derived from trimmings of fish already caught for human consumption in sustainable fisheries;

(d) organic feed materials of plant origin and of animal origin as listed in Annex V and the restriction laid down therein are complied with.

2. If feed mentioned under paragraph 1 is not available, fishmeal and fish oil from non-organic aquaculture trimmings, or trimmings of fish caught for human consumption may be used for a transitional period until 31



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December 2014. Such feed material shall not exceed 30 % of the daily ration.

3. The feed ration may comprise a maximum of 60 % organic plant products.

4. Astaxanthin derived primarily from organic sources, such as organic crustacean shells may be used in the feed ration for salmon and trout within the limit of their physiological needs. If organic sources are not available natural sources of astaxanthin (such as Phaffia yeast) may be used.

Article 251 Specific rules on feeds for certain aquaculture animals:

1. Aquaculture animals as referred to in Annex XIIIa, Section 6, Section 7 and Section 9 shall be fed with feed naturally available in ponds and lakes.

2. Where natural feed resources are not available in sufficient quantities as referred to in paragraph 1, organic feed of plant origin, preferably grown on the farm itself or seaweed may be used. Operators shall keep documentary evidence of the need to use additional feed.

3. Where natural feed is supplemented according to paragraph 2, the feed ration of species as mentioned in section 7 and of siamese catfish (Pangasius spp.) as mentioned in section 9 may comprise a maximum of 10 % fishmeal or fish oil derived from sustainable fisheries.

Article 25m Products and substances as referred to in EC No 834/2007 Article 15(1)(d)(iii): 1. Feed materials of animal and mineral origin may be used in organic aquaculture, only if listed in Annex V.

2. Feed additives, certain products used in animal nutrition and processing aids may be used if listed in Annex VI and the restrictions laid down therein are complied with.

Section 6 Specific rules for molluscs

Article 25n Growing area:

1. Bivalve mollusc farming may be carried out in the same area of water as organic finfish and seaweed farming in a polyculture system to be documented in the sustainable management plan. Bivalve molluscs may also be grown together with gastropod molluscs, such as periwinkles, in polyculture.

2. Organic bivalve mollusc production shall take place within areas delimited by posts, floats or other clear markers and shall, as appropriate, be restrained by net bags, cages or other man made means.

3. Organic shellfish farms shall minimise risks to species of conservation interest. If predator nets are used their design shall not permit diving birds to be harmed.

Article 250 Sourcing of seed:

1. Provided that there is no significant damage to the environment and if permitted by local legislation, wild seed from outside the boundaries of the production unit can be used in the case of bivalve shellfish provided it comes from.



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(a) settlement beds which are unlikely to survive winter weather or are surplus to requirements, or (b) natural settlement of shellfish seed on collectors.

Records shall be kept of how, where and when wild seed was collected to allow traceability back to the collection area.

However, seed from non-organic bivalve shellfish hatcheries may be introduced to the organic production units with the following maximum percentages: 80 % by 31 December 2011, 50 % by 31 December 2013 and 0 % by 31 December 2015.

2. For the cupped ovster, Crassostrea gigas, preference shall be given to stock which is selectively bred to reduce spawning in the wild.

Article 25p Management:

1. Production shall use a stocking density not in excess of that used for non-organic shellfish in the locality. Sorting, thinning and stocking density adjustments shall be made according to the biomass and to ensure animal welfare and high product quality.

2. Biofouling organisms shall be removed by physical means or by hand and where appropriate returned to the sea away from shellfish farms. Shellfish may be treated once during the production cycle with a lime solution to control competing fouling organisms.

Article 25q Cultivation rules:

1. Cultivation on mussel ropes and other methods listed in Annex XIIIa, Section 8 may be eligible for organic production.

2. Bottom cultivation of molluscs is only permitted where no significant environmental impact is caused at the collection and growing sites. The evidence of minimal environmental impact shall be supported by a survey and report on the exploited area to be provided by the operator to the certification body. The report shall be added as a separate chapter to the sustainable management plan.

Article 25r Specific cultivation rules for oysters:

Cultivation in bags on trestles is permitted. These or other structures in which the oysters are contained shall be set out so as to avoid the formation of a total barrier along the shoreline. Stock shall be positioned carefully on the beds in relation to tidal flow to optimise production. Production shall meet the criteria listed in the Annex XIIIa, Section 8.

Section 7 Disease prevention and veterinary treatment

Article 25s General rules on disease prevention:

1. The animal health management plan shall detail biosecurity and disease prevention practices including a written agreement for health counselling, proportionate to the production unit, with qualified aquaculture animal



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health services who shall visit the farm at a frequency of not less than once per year and not less than once every two years in the case of bivalve shellfish.

2. Holding systems, equipment and utensils shall be properly cleaned and disinfected. Only products listed in Annex VII, Sections 2.1 to 2.2 may be used.

3. With regard to fallowing:

(a) The certification body shall determine whether fallowing is necessary and the appropriate duration which shall be applied and documented after each production cycle in open water containment systems at sea. Fallowing is also recommended for other production methods using tanks, fishponds, and cages; (b) it shall not be mandatory for bivalve mollusc cultivation;

(c) during fallowing the cage or other structure used for aquaculture animal production is emptied, disinfected and left empty before being used again.

4. Where appropriate, uneaten fish-feed, faeces and dead animals shall be removed promptly to avoid any risk of significant environmental damage as regards water status quality, minimize disease risks, and to avoid attracting insects or rodents.

5. Ultraviolet light and ozone may be used only in hatcheries and nurseries.

6. For biological control of ectoparasites preference shall be given to the use of cleaner fish.

Article 25t Veterinary treatments:

1. When despite preventive measures to ensure animal health, according to EC No 834/2007 Article 15(1)(f)(i), a health problem arises, veterinary treatments may be used in the following order of preference:

(a) substances from plants, animals or minerals in a homoeopathic dilution;

(b) plants and their extracts not having anaesthetic effects, and

(c) substances such as: trace elements, metals, natural immunostimulants or authorised probiotics.

2. The use of allopathic treatments is limited to two courses of treatment per year, with the exception of vaccinations and compulsory eradication schemes. However, in the cases of a production cycle of less than a year a limit of one allopathic treatment applies. If the mentioned limits for allopathic treatments are exceeded the concerned aquaculture animals can not be sold as organic products.

3. The use of parasite treatments shall be limited to twice per year or once per year where the production cycle is less than 18 months.

4. The withdrawal period for allopathic veterinary treatments and parasite treatments according to paragraph 3 including treatments under compulsory control and eradication schemes shall be twice the legal withdrawal period as referred to by national regulation(s) or, in a case in which this period in not specified, 48 hours.

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Article 15 – Production rules for aquaculture animals

5. Whenever veterinary medicinal products are used, such use is to be declared to the certification body before the animals are marketed as organic. Treated stock shall be clearly identifiable.

EC No 834/2007 Title III – Production Rules CHAPTER 2 – Farm Production

Article 16 – Products and substances used in farming and criteria for their authorisation

1. The Commission shall authorise for use in organic production and include in a restricted list the products and substances, which may be used in organic farming for the following purposes:

(a) as plant protection products;

(b) as fertilisers and soil conditioners;

(c) as non-organic feed materials from plant origin, feed material from animal and mineral origin and certain substances used in animal nutrition;

(d) as feed additives and processing aids;

(e) as products for cleaning and disinfection of ponds, cages, buildings and installations for animal production;

(f) as products for cleaning and disinfection of buildings and installations used for plant production, including storage on an agricultural holding.

Products and substances contained in the restricted list may only be used in so far as the corresponding use is authorised in general agriculture in the country concerned in accordance with relevant national regulation(s).

EC 889/2008

Article 95 Transitional measures, paragraph 6:

6. For the purpose of EC No 834/2007 Article 12(1)(j) and pending the inclusion of specific substances according to Article 16(1)(f) of that Regulation, only products authorised by the certification body may be used.

Key Comment 20

Prior to authorization, the certification body must verify the products are allowed by the EU for the specific purpose and in accordance with relevant national regulations.

2. The authorisation of the products and substances referred to in paragraph 1 is subject to the objectives and principles laid down in Title II and the following general and specific criteria which shall be evaluated as a whole:

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Article 16 – Products and substances used in farming and criteria for their authorisation

(a) their use is necessary for sustained production and essential for its intended use;

(b) all products and substances shall be of plant, animal, microbial or mineral origin except where products or substances from such sources are not available in sufficient quantities or qualities or if alternatives are not available;

(c) in the case of products referred to in paragraph 1(a), the following shall apply:

(i) their use is essential for the control of a harmful organism or a particular disease for which other biological, physical or breeding alternatives or cultivation practices or other effective management practices are not available;

(ii) if products are not of plant, animal, microbial or mineral origin and are not identical to their natural form, they may be authorised only if their conditions for use preclude any direct contact with the edible parts of the crop;

(d) in the case of products referred to in paragraph 1(b), their use is essential for obtaining or maintaining the fertility of the soil or to fulfil specific nutrition requirements of crops, or specific soil-conditioning purposes;

(e) in the case of products referred to in paragraph 1(c) and (d), the following shall apply:

(i) they are necessary to maintain animal health, animal welfare and vitality and contribute to an appropriate diet fulfilling the physiological and behavioural needs of the species concerned or it would be impossible to produce or preserve such feed without having recourse to such substances;

(ii) feed of mineral origin, trace elements, vitamins or provitamins shall be of natural origin. In case these substances are unavailable, chemically well-defined analogic substances may be authorised for use in organic production.

3(a) The Commission may lay down conditions and limits as regards the agricultural products to which the products and substances referred to in paragraph 1 can be applied to, the application method, the dosage, the time limits for use and the contact with agricultural products and, if necessary, decide on the withdrawal of these products and substances...

(c) Products and substances used before adoption of this Regulation for purposes corresponding to those laid down in paragraph 1 of this Article, may continue to be used after said adoption. The Commission may in any case withdraw such products or substances...

5. The use of products and substances not covered under paragraph 1 and 4, and subject to the objectives and principles laid down in Title II and the general criteria in this Article, shall be allowed in organic farming.



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EC No 834/2007 Title III – Production Rules CHAPTER 2 – Farm Production

Article 17 – Conversion

1. The following rules shall apply to a farm on which organic production is started:

(a) the conversion period shall start at the earliest when the operator has notified his activity to the competent authorities and subjected his holding to the control system in accordance with Article 28(1);

(b) during the conversion period all rules established by this EC No 834/2007 shall apply;

(c) conversion periods specific to the type of crop or animal production shall be defined;

EC 889/2008

Article 36 Plant and plant products:

1. For plants and plant products to be considered organic, the production rules as referred to in EC No 834/2007 Articles 9, 10, 11 and 12 and EC No 889/2008 Chapter 1, and where applicable, the exceptional production rules in EC No 889/2008 Chapter 6 must have been applied on the parcels during a conversion period of at least two years before sowing, or, in the case of grassland or perennial forage, at least two years before its use as feed from organic farming, or, in the case of perennial crops other than forage, at least three years before the first harvest of organic products.

2. The certification body may decide to recognise retroactively as being part of the conversion period any previous period in which:

(a) the land parcels were registered in an official environmental protection or similar program, provided that the measures concerned ensure that products not authorised for organic production have not been used on those parcels, or

(b) the parcels were natural or agricultural areas which were not treated with products not authorised for organic production.

The period referred to in point (b) of the first subparagraph can be taken into consideration retroactively only where satisfactory proof has been furnished to the certification body allowing it to satisfy itself that the conditions were met for a period of at least three years.

3. The certification body may decide, in certain cases, where the land had been contaminated with products not authorised for organic production, to extend the conversion period beyond the period referred to in paragraph 1.

Article 36a Seaweed:

1. The conversion period for a seaweed harvesting site shall be six months.

2. The conversion period for a seaweed cultivation unit shall be the longer of six months or one full production cycle.



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Article 17 – Conversion

Article 37 Specific conversion rules for land associated with organic livestock production:

1. The conversion rules as referred to in EC No 889/2008 Article 36 shall apply to the whole area of the production unit on which animal feed is produced.

2. Notwithstanding the provisions in paragraph 1, the conversion period may be reduced to one year for pasturages and open air areas used by non-herbivore species. This period may be reduced to six months where the land concerned has not during the last year, received treatments with products not authorised for organic production.

Article 38 Livestock and livestock products:

1. Where non-organic livestock has been brought onto a holding in accordance with EC No 834/2007 Article 14(1)(a)(ii) and EC No 889/2008 Article 9 and/or EC No 889/2008 Article 42 and if livestock products are to be sold as organic products, the production rules as referred to in EC No 834/2007 Articles 9, 10, 11 and 14 and in EC No 889/2008 Chapter 2 of Title II and where applicable in EC No 889/2008 Article 42 must have been applied for at least:

(a) 12 months in the case of equidae and bovines, including *bubalus* and bison species, for meat production, and in any case at least three quarters of their lifetime;

(b) six months in the case of small ruminants and pigs and animals for milk production;

(c) 10 weeks for poultry for meat production, brought in before they are three days old;

(d) six weeks in the case of poultry for egg production.

2. Where non-organic animals exist on a holding at the beginning of the conversion period in accordance with EC No 834/2007 Article 14(1)(a)(iii), their products may be deemed organic if there is simultaneous conversion of the complete production unit, including livestock, pasturage and/or any land used for animal feed. The total combined conversion period for both existing animals and their offspring, pasturage and/or any land used for animal feed animal feed, may be reduced to 24 months, if the animals are mainly fed with products from the production unit.

3. Beekeeping products can be sold with references to the organic production method only when the organic production rules have been complied with for at least one year.

4. The conversion period for apiaries does not apply in the case of application of EC No 889/2008 Article 9(5).

5. During the conversion period the wax shall be replaced with wax coming from organic beekeeping.

Article 38a Aquaculture animal production:

1. The following conversion periods for aquaculture production units shall apply for the following types of aquaculture facilities including the existing aquaculture animals:

(a) for facilities that cannot be drained, cleaned and disinfected, a conversion period of 24 months:



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Article 17 – Conversion

(b) for facilities that have been drained, or fallowed, a conversion period of 12 months;

(c) for facilities that have been drained, cleaned and disinfected a conversion period of six months;

(d) for open water facilities including those farming bivalve molluscs, a three month conversion period.

2. The certification body may decide to recognize retroactively as being part of the conversion period any previously documented period in which the facilities were not treated or exposed to products not authorized for organic production.

Article 42 Use of non-organic animals:

Where the conditions laid down in EC No 834/2007 Article 22(2)(b) apply, and with prior authorisation of the certification body,

(a) when a flock is constituted for the first time, renewed or reconstituted and organically reared poultry are not available in sufficient numbers, non-organically reared poultry may be brought into an organic poultry production unit, provided that the pullets for the production of eggs and poultry for meat production are less than three days old;

(b) non-organically reared pullets for egg production of not more than 18 weeks may be brought into an organic livestock unit until 31 December 2011, when organically reared pullets are not available and provided that the relevant provisions laid down in Section 3 and 4 of Chapter 2 are complied with.

Key Comment 21

Important: Article 42 only applies if the operation has obtained prior authorization from the certification body (Section 3 Feed / Section 4 Disease Prevention and Veterinary Treatment).

(d) on a holding or unit partly under organic production and partly in conversion to organic production, the operator shall keep the organically produced and in-conversion products separate and the animals separate or readily separable and keep adequate records to show the separation;

(e) in order to determine the conversion period referred to above, a period immediately preceding the date of the start of the conversion period, may be taken into account, in so far as certain conditions concur;

(f) animals and animal products produced during the conversion period referred to in subparagraph (c) shall not be marketed with the indications referred to in Articles 23 and 24 used in the labelling and advertising of products.



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EC No 834/2007 Title III – Production Rules CHAPTER 3 – Production of processed feed

Article 18 – General rules on the production of processed feed

- 1. Production of processed organic feed shall be kept separate in time or space from production of processed non organic feed.
- 2. Organic feed materials, or feed materials from production in conversion, shall not enter simultaneously with the same feed materials produced by non organic means into the composition of the organic feed product.
- 3. Any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesised solvents.
- 4. Substances and techniques that reconstitute properties that are lost in the processing and storage of organic feed, that correct the results of negligence in the processing or that otherwise may be misleading as to the true nature of these products shall not be used.

EC 889/2008

Article 26 Rules for the production of processed feed and food: 1. Additives, processing aids and other substances and ingredients used for processing food or feed and any

processing practice applied, such as smoking, shall respect the principles of good manufacturing practice.

2. Operators producing processed feed or food shall establish and update appropriate procedures based on a systematic identification of critical processing steps.

3. The application of the procedures referred to in paragraph 2 shall guarantee at all times that the produced processed products comply with the organic production rules.

4. Operators shall comply with and implement the procedures referred to in paragraph 2. In particular, operators shall:

(a) take precautionary measures to avoid the risk of contamination by unauthorised substances or products;

(b) implement suitable cleaning measures, monitor their effectiveness and record these operations;

(c) guarantee that non-organic products are not placed on the market with an indication referring to the organic production method.

5. Further to the provisions laid down in paragraphs 2 and 4, when non-organic products are also prepared or stored in the preparation unit concerned, the operator shall:

(a) carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations performed on non-organic products;

(b) store organic products, before and after the operations, separate by place or time from non-organic products;



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Article 18 – General rules on the production of processed feed

(c) inform the certification body thereof and keep available an updated register of all operations and quantities processed:

(d) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with nonorganic products;

(e) carry out operations on organic products only after suitable cleaning of the production equipment.

EC No 834/2007 **Title III – Production Rules CHAPTER 4 – Production of processed food**

Article 19 – General rules on the production of processed food

1. The preparation of processed organic food shall be kept separate in time or space from non-organic food.

EC 889/2008

Article 26 Rules for the production of processed feed and food, paragraphs 2-5: 2. Operators producing processed feed or food shall establish and update appropriate procedures based on a systematic identification of critical processing steps.

3. The application of the procedures referred to in paragraph 2 shall guarantee at all times that the produced processed products comply with the organic production rules.

4. Operators shall comply with and implement the procedures referred to in paragraph 2. In particular, operators shall:

(a) take precautionary measures to avoid the risk of contamination by unauthorised substances or products;

(b) implement suitable cleaning measures, monitor their effectiveness and record these operations;

(c) guarantee that non-organic products are not placed on the market with an indication referring to the organic production method.

5. Further to the provisions laid down in paragraphs 2 and 4, when non-organic products are also prepared or stored in the preparation unit concerned, the operator shall:

(a) carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations performed on non-organic products:



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Article 19 – General rules on the production of processed food

(b) store organic products, before and after the operations, separate by place or time from non-organic products;

(c) inform the certification body thereof and keep available an updated register of all operations and quantities processed;

(d) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with nonorganic products;

(e) carry out operations on organic products only after suitable cleaning of the production equipment.

Key Comment 22

The EU standards are more prescriptive in the requirements for the preparation of organic food.

NOP §205.272 - requires the operation to implement measures to prevent comingling of organic and nonorganic products and protect organic products from coming into contact with prohibited substances.

Food safety concerns and proper sanitation (good manufacturing practices) must be followed. Per PM 11-6 Reporting Health and Safety Violations, certifying agents are obligated to report violations of health or safety to the appropriate local, State, or Federal officials. A copy of all such reporting shall be forwarded to the NOP. Certification shall not be granted or continued when current health or safety inspections have not been granted or renewed for the facility.

(Note regarding 889/2008 5(a) and 5(b): Some ACAs require controls in place for separation and *identification while others require a different processing room or storage area.*)

2. The following conditions shall apply to the composition of organic processed food:

(a) the product shall be produced mainly from ingredients of agricultural origin; in order to determine whether a product is produced mainly from ingredients of agricultural origin added water and cooking salt shall not be taken into account;

(b) only additives, processing aids, flavourings, water, salt, preparations of micro-organisms and enzymes, minerals, trace elements, vitamins, as well as amino acids and other micronutrients in foodstuffs for particular nutritional uses may be used, and only in so far as they have been authorised for use in organic production in accordance with Article 21;

EC 889/2008

Article 26 Rules for the production of processed feed and food, paragraph 1: 1. Additives, processing aids and other substances and ingredients used for processing food or feed and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice.

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Article 19 – General rules on the production of processed food

Article 27 Use of certain products and substances in processing of food:

1. For the purpose of EC No 834/2007 Article 19(2)(b), only the following substances can be used in the processing of organic food, with the exception of wine:

(a) substances listed in Annex VIII to this Regulation;

(b) preparations of micro-organisms and enzymes normally used in food processing; however, enzymes to be used as food additives have to be listed in Annex VIII, Section A.

(c) substances, and products as defined in Articles 1(2)(b)(i) and 1(2)(c) of Council Directive 88/388/EEC labelled as natural flavouring substances or natural flavouring preparations, according to Articles 9(1)(d) and (2) of that Directive.

From Directive $\frac{88}{388}$ /EEC Articles 1(2)(b)(i) and 1(2)(c):

2. For the purposes of this Directive:

(b) 'flavouring substance' means a defined chemical substance with flavouring properties which is obtained:

(i) by appropriate physical processes (including distillation and solvent extraction) or enzymatic or microbiological processes from material of vegetable or animal origin either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and *fermentation*).

(c) 'flavouring preparation' means a product, other than the substances defined in (b) (i), whether concentrated or not, with flavouring properties, which is obtained by appropriate physical processes (including distillation and solvent extraction) or by enzymatic or microbiological processes from material of vegetable or animal origin, either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation);

From Directive 88/388/EEC Articles 9(1)(d) and (2):

1. Flavourings not intended for sale to the final consumer may not be marketed unless their packagings or containers bear the following information, which should be easily visible, clearly legible and indelible:

(d) a list in descending order of weight of the categories of flavouring substances and flavouring preparations present classified as follows:

- natural flavouring substances in the case of flavouring substances defined in Article 1(2)(b)(i),

- flavouring preparations in the case of preparations defined in Article 1 (2) (c),

2. Without prejudice to paragraph 1 (d), the word 'natural', or any other word having substantially the same meaning, may be used only for flavourings in which the flavouring component contains exclusively flavouring



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substances as defined in Article 1 (2) (b) (i) and/or flavouring preparations as defined in Article 1 (2) (c).

If the sales description of the flavouring contains a reference to a foodstuff or a flavouring source, the word 'natural', or any other word having substantially the same meaning, may not be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food preparation processes solely or almost solely from the foodstuff or the flavouring source concerned.

(d) colours for stamping meat and eggshells in accordance with, respectively, Article 2(8) and Article 2(9) of European Parliament and Council Directive 94/36/EC;

From Directive 94/36/EC Article 2(8) and Article 2(9):

8. For the purpose of health marking as provided in Directive 91/497/EEC and other marking required on meat products, only E 155 Brown HT, E 133 Brilliant Blue FCF or E 129 Allura Red AC or an appropriate mixture of E 133 Brillaint Blue FCF and E 129 Allura Red AC may be used.

9. Only those colours mentioned in Annex 1 may be used for the decorative colouring of eggshells or for the stamping of eggshells as provided in Regulation (EEC) No 1274/91.

Key Comment 23

Although Directive 94/36/EC is specific to Member States, certified operations outside of the Member States must adhere to the requirements if product is to be exported to the Member States. Annex 1 – List of Permitted Food Colours of 94/36/EC contained as attachment.

(e) drinking water and salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;

(f) minerals (trace elements included), vitamins, amino acids, and micronutrients, only authorised as far their use is legally required in the foodstuffs in which they are incorporated.

2. For the purpose of the calculation referred to in EC No 834/2007 Article 23(4)(a)(ii),

(a) food additives listed in Annex VIII and marked with an asterisk in the column of the additive code number, shall be calculated as ingredients of agricultural origin;

(b) preparations and substances referred to in paragraph (1)(b),(c),(d),(e) and (f) of this Article and substances not marked with an asterisk in the column of the additive code number shall not be calculated as ingredients of agricultural origin.

(c) yeast and yeast products shall be calculated as ingredients of agricultural origin as of 31 December 2013...



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Key Comment 24

Key Difference: NOP §205.301(f)(5) states, "(f) All products labeled as "100 percent organic" or "organic" and all ingredients identified as "organic" in the ingredient statement of any product must not: (5) Contain sulfites, nitrates, or nitrites added during the production or handling process, Except, that, wine containing added sulfites may be labeled "made with organic grapes."

Key Difference: NOP §205.605(b) states, "Sulfur dioxide—for use only in wine labeled "made with organic grapes," Provided, That, total sulfite concentration does not exceed 100 ppm."

Key Difference: NOP §205.105(c) states, "To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of: Nonagricultural substances used in or on processed products, except as otherwise provided in §205.605." Hydrochloric acid is not listed under 205.605.

The following substances listed in Annex VIII shall be re-examined by the Commission: sodium nitrite and potassium nitrate in Section A; sulphur dioxide and potassium metabisulphite in Section A; and hydrochloric acid in Section B for the processing of Gouda, Edam and Maasdammer cheeses, Boerenkaas, Friese, and Leidse Nagelkaas.

4. For the traditional decorative colouring of the shell of boiled eggs produced with the intention to place them on the market at a given period of the year, the certification body may authorise for the period referred to above, the use of natural colours and natural coating substances. The authorisation may comprise synthetic forms of iron oxides and iron hydroxides until 31 December 2013.

(c) non-organic agricultural ingredients may be used only if they have been authorised for use in organic production in accordance with Article 21 or have been provisionally authorised by a certification body;

EC 889/2008

Article 28 Use of certain non-organic ingredients of agricultural origin in processing food: For the purpose of Article 19(2)(c) of Regulation (EC) No 834/2007, non-organic agricultural ingredients listed in Annex IX to this Regulation can be used in the processing of organic food.

Article 29 Authorisation of non-organic food ingredients of agricultural origin:

1. Where an ingredient of agricultural origin is not included in Annex IX to this Regulation, that ingredient may only be used under the following conditions:

(a) the operator has notified to the certification body all the requisite evidence showing that the ingredient concerned is not produced in sufficient quantity and cannot be obtained in organic form, or cannot be imported from third countries;

(b) the certification body has provisionally authorised, the use for a maximum period of 12 months after having verified that the operator has undertaken the necessary contacts with suppliers to ensure himself of the unavailability of the ingredients concerned with the required quality requirements;...



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Article 19 – General rules on the production of processed food

The certification body may prolong the authorisation provided for in point (b) a maximum of three times for 12 months each.

2. Where an authorisation as referred to in paragraph 1 has been granted, the certification body shall maintain a record of the authorization which includes the following information:

(a) the date of the authorisation and in case of a prolonged authorisation, the date of the first authorisation;

(b) the name, address, telephone, and where relevant, fax and e-mail of the holder of the authorisation; the name and address of the contact point of the authority which granted the authorisation;

(c) the name and, where necessary, the precise description and quality requirements of the ingredient of agricultural origin concerned;

(d) the type of products for the preparation of which the requested ingredient is necessary;

(e) the quantities that are required and the justification for those quantities;

(f) the reasons for, and expected period of, the shortage...;

5. In case of an extension as referred to in the second subparagraph of paragraph 1, the procedures of paragraph 2 shall apply.

(d) an organic ingredient shall not be present together with the same ingredient in non-organic form or an ingredient in conversion;

(e) food produced from in-conversion crops shall contain only one crop ingredient of agricultural origin.

3. Substances and techniques that reconstitute properties that are lost in the processing and storage of organic food, that correct the results of negligence in the processing of these products or that otherwise may be misleading as to the true nature of these products shall not be used.

EC No 834/2007 **Title III – Production Rules** CHAPTER 4 – Production of processed food

Article 20 – General rules on the production of organic yeast

1. For the production of organic yeast only organically produced substrates shall be used. Other products and substances may only be used in so far as they have been authorised for use in organic production in accordance with Article 21.



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EC No 834/2007 **Title III – Production Rules CHAPTER 4 – Production of processed food**

Article 20 - General rules on the production of organic yeast

2. Organic yeast shall not be present in organic food or feed together with non-organic yeast.

EC 889/2008

Article 27a:

For the purpose of the application of EC No 834/2007 Article 20 (1), the following substances may be used in the production, confection and formulation of yeast:

(a) substances listed in Annex VIII, Section C to this Regulation;

(b) products and substances referred to in Article 27 (1) (b) and (e) of this Regulation...

EC No 834/2007 **Title III – Production Rules CHAPTER 4 – Production of processed food**

Article 21 – Criteria for certain products and substances in processing

1. The authorisation of products and substances for use in organic production and their inclusion in a restricted list of the products and substances referred to in Article 19(2)(b) and (c) shall be subject to the objectives and principles laid down in Title II and the following criteria, which shall be evaluated as a whole:

(i) alternatives authorised in accordance with this chapter are not available;

(ii) without having recourse to them, it would be impossible to produce or preserve the food or to fulfill given dietary requirements provided for on the basis of the Community legislation.

In addition, the products and substances referred to in Article 19(2)(b) are to be found in nature and may have undergone only mechanical, physical, biological, enzymatic or microbial processes, except where such products and substances from such sources are not available in sufficient quantities or qualities on the market.

2. The Commission shall decide on the authorisation of the products and substances and their inclusion in the restricted list referred to in paragraph 1 of this Article and lay down specific conditions and limits for their use, and, if necessary, on the withdrawal of products...

Products and substances used before adoption of this Regulation and falling under Article 19(2)(b) and (c) may continue to be used after the said adoption. The Commission may, in any case, withdraw such products or substances.



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EC No 834/2007 **Title III – Production Rules CHAPTER 4 – Production of processed food**

Article 21 – Criteria for certain products and substances in processing

EC 889/2008

Preamble paragraph 7:

(7) For the purpose of organic farming, the use of certain plant protection products, fertilisers, soil conditioners, as well as certain non-organic feed materials, feed additives and feed processing aids and certain products used for cleaning and disinfection was allowed under Council Regulation (EEC) No 2092/91 under well-defined conditions. For the sake of ensuring the continuity of organic farming the products and substances in question should, in accordance with the provisions laid down in EC No 834/2007 Article 16(3)(c), continue to be allowed. Moreover, for the sake of clarity, it is appropriate to list in the Annexes to this Regulation the products and substances which had been allowed under Regulation (EEC) No 2092/91. Other products and substances may be added to these lists in the future under a different legal basis, namely EC No 834/2007 Article 16(1). It is therefore appropriate to identify the distinct status of each category of products and substances by means of a symbol in the list.

EC No 834/2007 **Title III – Production Rules CHAPTER 5 – Flexibility**

Article 22 – Exceptional production rules

1. The Commission may, in accordance with the conditions set out in paragraph 2 of this Article and subject to the objectives and principles laid down in Title II, provide for the granting of exceptions from the production rules laid down in Chapters 1 to 4.

2. Exceptions as referred to in paragraph 1 shall be kept to a minimum and, where appropriate, limited in time and may only be provided for in the following cases:

(a) where they are necessary in order to ensure that organic production can be initiated or maintained on holdings confronted with climatic, geographical or structural constraints;

EC 889/2008

Article 40 Parallel production:

1. A producer may run organic and non-organic production units in the same area:

(a) in the case of the production of perennial crops, which require a cultivation period of at least three years, where varieties cannot be easily differentiated, provided the following conditions are met:

(i) the production in question forms part of a conversion plan in respect of which the producer gives a firm undertaking and which provides for the beginning of the conversion of the last part of the area concerned to organic production in the shortest possible period which may not in any event exceed a maximum of five years:

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(ii) appropriate measures have been taken to ensure the permanent separation of the products obtained from each unit concerned;

(iii) the certification body is notified of the harvest of each of the products concerned at least 48 hours in advance;

(iv) upon completion of the harvest, the producer informs the certification body of the exact quantities harvested on the units concerned and of the measures applied to separate the products;

(v) the conversion plan and the control measures referred to in Chapter 1 and 2 of Title IV have been approved by the certification body; this approval shall be confirmed each year after the start of the conversion plan;

(b) in the case of areas intended for agricultural research or formal education and provided the conditions set out in point (a)(ii)(iii)(iv) and the relevant part of point (v) are met;

(c) in the case of production of seed, vegetative propagating material and transplants and provided the conditions set out in point (a)(ii)(iii)(iv) and the relevant part of point (v) are met;

(d) in the case of grassland exclusively used for grazing.

2. The certification body may authorise holdings carrying out agricultural research or formal education to rear organic and non-organic livestock of the same species, where the following conditions are met:

(a) appropriate measures, notified in advance to the certification body, have been taken in order to guarantee the permanent separation between livestock, livestock products, manure and feedingstuffs of each of the units;

(b) the producer informs the certification body in advance of any delivery or selling of the livestock or livestock products;

(c) the operator informs the certification body of the exact quantities produced in the units together with all characteristics permitting the identification of the products and confirms that the measures taken to separate the products have been applied.

(b) where it is necessary in order to ensure access to feed, seed and vegetative propagating material, live animals and other farm inputs, where such inputs are not available on the market in organic form;

EC 889/2008

Article 45 Use of seed or vegetative propagating material not obtained by the organic production method: 1.(a) seed and vegetative propagating material from a production unit in conversion to organic farming may be used,

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Article 22 – Exceptional production rules

Key Comment 25

Key difference: NOP requires organic seed and planting stock (vegetative propagating material) unless not commercially available in organic form and does not address seed or planting stock in reference to land in transition to organic.

(b) where point (a) is not applicable, certification bodies may authorise the use of non-organic seed or vegetative propagating material if not available from organic production. However, for the use of non-organic seed and seed potatoes the following paragraphs (2) to (9) apply.

2. Non-organic seed and seed potatoes may be used, provided that the seed or seed potatoes are not treated with plant protection products, other than those authorised for treatment of seed in accordance with Article 5(1), unless chemical treatment is prescribed in accordance with Council Directive 2000/29/EC for phytosanitary purposes by the competent authority of the Member State for all varieties of a given species in the area where the seed or seed potatoes are to be used.

Key Comment 26

Important: If seed or seed potatoes are treated with anything due to a phytosanitary requirement of a third country, the certification body must verify that the use of the product is allowed either for organic production in accordance with EC No 834 and/or EC No 889 or by the Member State(s) where the product is to be exported.

3. Species for which it is established that organically produced seed or seed potatoes are available in sufficient quantities and for a significant number of varieties in all parts of the Community are set out in Annex X. The species listed in Annex X may not be subject of authorisations pursuant to paragraph 1(b), unless these are justified by one of the purposes referred to in paragraph 5(d)...

Key Comment 27

Annex X does not contain any species at this time.

5. Authorisation to use seed or seed potatoes not obtained by the organic production method may only be granted in the following cases:

(a) where no variety of the species which the user wants to obtain is registered in the database referred to in Article 48:

(b) where no supplier, meaning an operator who markets seed or seed potatoes to other operators, is able to deliver the seed or seed potatoes before sowing or planting in situations where the user has ordered the seed or seed potatoes in reasonable time;

(c) where the variety which the user wants to obtain is not registered in the database referred to in Article 48, and the user is able to demonstrate that none of the registered alternatives of the same species are appropriate and that the authorisation therefore is significant for his production:



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(d) where it is justified for use in research, test in small-scale field trials or for variety conservation purposes agreed by the certification body.

6. The authorisation shall be granted before the sowing of the crop.

7. The authorisation shall be granted only to individual users for one season at a time and the certification body responsible for the authorisations shall register the quantities of seed or seed potatoes authorised.

8. By way of derogation from paragraph 7, the certification body may grant to all users a general authorisation:

(a) for a given species when and in so far as the condition laid down in paragraph 5(a) is fulfilled;

(b) for a given variety when and in so far as the conditions laid down in paragraph 5(c) are fulfilled.

The authorisations referred to in the first subparagraph shall be clearly indicated in the database referred to in Article 48.

9. Authorisation may only be granted during periods for which the database is updated in accordance with Article 49(3).

Key Comment 28

The establishment of a database referred to in Article 48 is specific to Member States. However, for the application of this requirement, certification bodies should refer to databases to source seed or seed potatoes for use in organic production.

(c) where it is necessary in order to ensure access to ingredients of agricultural origin, where such ingredients are not available on the market in organic form;

EC 889/2008

Article 29 Authorisation of non-organic food ingredients of agricultural origin:1. Where an ingredient of agricultural origin is not included in Annex IX to this Regulation, that ingredient may only be used under the following conditions:

(a) the operator has notified to the certification body all the requisite evidence showing that the ingredient concerned is not produced in sufficient quantity and cannot be obtained in organic form, or cannot be imported from third countries;

(b) the certification body has provisionally authorised, the use for a maximum period of 12 months after having verified that the operator has undertaken the necessary contacts with suppliers to ensure himself of the unavailability of the ingredients concerned with the required quality requirements;...

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The certification body may prolong the authorisation provided for in point (b) a maximum of three times for 12 months each.

2. Where an authorisation as referred to in paragraph 1 has been granted, the certification body shall maintain a record of the authorization which includes the following information:

(a) the date of the authorisation and in case of a prolonged authorisation, the date of the first authorisation;

(b) the name, address, telephone, and where relevant, fax and e-mail of the holder of the authorisation; the name and address of the contact point of the authority which granted the authorisation;

(c) the name and, where necessary, the precise description and quality requirements of the ingredient of agricultural origin concerned;

(d) the type of products for the preparation of which the requested ingredient is necessary;

(e) the quantities that are required and the justification for those quantities;

(f) the reasons for, and expected period of, the shortage...;

5. In case of an extension as referred to in the second subparagraph of paragraph 1, the procedures of paragraph 2 shall apply.

(d) where they are necessary in order to solve specific problems related to the management of organic livestock;

EC 889/2008

Article 46 Specific management problems in organic livestock: The final fattening phase of adult bovines for meat production may take place indoors, provided that this indoors period does not exceed one fifth of their lifetime and in any case for a maximum period of three months.

(e) where they are necessary with regard to the use of specific products and substances in the processing referred to in Article 19(2)(b) in order to ensure production of well established food products in organic form;

EC 889/2008

Article 46a Addition of non-organic yeast extract:

The addition of up to 5 % non-organic yeast extract or autolysate to the substrate (calculated in dry matter) is allowed for the production of organic yeast, where operators are unable to obtain yeast extract or autolysate from organic production.

Key Comment 29

The availability of organic yeast extract or autolysate is to be re-examined by December 31, 2013 with a view to withdrawing this provision.



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(f) where temporary measures are necessary in order to allow organic production to continue or recommence in the case of catastrophic circumstances;

EC 889/2008

Article 47 Catastrophic circumstances:

The certification body may authorise on a temporary basis:

(a) in the case of high mortality of animals caused by health or catastrophic circumstances, the renewal or reconstitution of the herd or flock with non-organic animals, when organically reared animals are not available;

(b) in case of high mortality of bees caused by health or catastrophic circumstances, the reconstitution of the apiaries with non-organic bees, when organic apiaries are not available;

(c) the use of non-organic feedingstuffs for a limited period and in relation to a specific area by individual operators, when forage production is lost or when restrictions are imposed, in particular as a result of exceptional meteorological conditions, the outbreak of infectious diseases, the contamination with toxic substances, or as a consequence of fires;

(d) the feeding of bees with organic honey, organic sugar or organic sugar syrup in case of long lasting exceptional weather conditions or catastrophic circumstances, which hamper the nectar or honeydew production.

Upon approval by the certification body, the individual operators shall keep documentary evidence of the use of the above exceptions.

(g) where it is necessary to use food additives and other substances as set out in Article 19(2)(b) or feed additives and other substances as set out in Article 16(1)(d) and such substances are not available on the market other than produced by GMOs;

(h) where the use of food additives and other substances as set out in Article 19(2)(b) or feed additives as set out in Article 16(1)(d) is required on the basis of Community law or national law.

EC 889/2008

Key Comment 30

EC No 889/2008 Articles 30, 31, 32, 33, and 35 apply to the collection, packaging, transport, reception and storage of all types of organic products as specified within the articles.

Article 34 is specific to the EU Community. The GV Division does not assess certification bodies against the requirements within this Article. As a result, Article 34 is not included within this document.

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Article 30 Collection of products and transport to preparation units:

Operators may carry out simultaneous collection of organic and non-organic products, only where appropriate measures are taken to prevent any possible mixture or exchange with non-organic products and to ensure the identification of the organic products. The operator shall keep the information relating to collection days, hours, circuit and date and time of reception of the products available to the certification body.

Article 31 Packaging and transport of products to other operators or units:

1. Operators shall ensure that organic products are transported to other units, including wholesalers and retailers, only in appropriate packaging, containers or vehicles closed in such a manner that substitution of the content cannot be achieved without manipulation or damage of the seal and provided with a label stating, without prejudice to any other indications required by law:

(a) the name and address of the operator and, where different, of the owner or seller of the product;

(b) the name of the product or a description of the compound feedingstuff accompanied by a reference to the organic production method;

(c) the name and/or the code number of the certification body to which the operator is subject; and

(d) where relevant, the lot identification mark according to a marking system either approved at national level or agreed with the certification body and which permits to link the lot with the accounts referred to in Article 66.

The information referred to in points (a) to (d) of the first subparagraph may also be presented on an accompanying document, if such a document can be undeniably linked with the packaging, container or vehicular transport of the product. This accompanying document shall include information on the supplier and/or the transporter.

2. The closing of packaging, containers or vehicles shall not be required where:

(a) transportation is direct between an operator and another operator who are both subject to the organic control system, and

(b) the products are accompanied by a document giving the information required under paragraph 1, and

(c) both the expediting and the receiving operators shall keep documentary records of such transport operations available for the certification body of such transport operations.

Article 32 Special rules for transporting feed to other production/preparation units or storage premises: In addition to the provisions of Article 31, when transporting feed to other production or preparation units or storage premises, operators shall ensure that the following conditions are met:

(a) during transport, organically-produced feed, in-conversion feed, and non-organic feed shall be effectively physically separated;

(b) the vehicles and/or containers which have transported non-organic products are used to transport organic products provided that:



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(i) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before commencing the transport of organic products; operators shall record these operations,

(ii) all appropriate measures are implemented, depending on the risks evaluated in accordance with Article 88(3) and, where necessary, operators shall guarantee that non-organic products cannot be placed on the market with an indication referring to organic production,

(iii) the operator shall keep documentary records of such transport operations available for the certification body;

(c) the transport of finished organic feed shall be separated physically or in time from the transport of other finished products;

(d) during transport, the quantity of products at the start and each individual quantity delivered in the course of a delivery round shall be recorded.

Article 32a Transport of live fish:

1. Live fish shall be transported in suitable tanks with clean water which meets their physiological needs in terms of temperature and dissolved oxygen.

2. Before transport of organic fish and fish products, tanks shall be thoroughly cleaned, disinfected and rinsed.

3. Precautions shall be taken to reduce stress. During transport, the density shall not reach a level which is detrimental to the species.

4. Documentary evidence shall be maintained for paragraphs 1 to 3.

Article 33 Reception of products from other units and other operators:

On receipt of an organic product, the operator shall check the closing of the packaging or container where it is required and the presence of the indications provided to in Article 31.

The operator shall crosscheck the information on the label referred to in Article 31 with the information on the accompanying documents. The result of these verifications shall be explicitly mentioned in the documentary accounts referred to in Article 66.

Article 35 Storage of products states:

1. For the storage of products, areas shall be managed in such a way as to ensure identification of lots and to avoid any mixing with or contamination by products and/or substances not in compliance with the organic production rules. Organic products shall be clearly identifiable at all times.

2. In case of organic plant, seaweed, livestock and aquaculture animal production units, storage of input products other than those authorised under this Regulation is prohibited in the production unit.

3. The storage of allopathic veterinary medicinal products and antibiotics is permitted on holdings provided that they have been prescribed by a veterinarian in connection with treatment as referred to in EC No 834/2007 Articles 14(1)(e)(ii) or 15(1)(f)(ii), that they are stored in a supervised location and that they are entered in the livestock record as referred to in Article 76 of this Regulation, or as appropriate, in the aquaculture production



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records as referred to in Article 79b of this Regulation.

4. In case where operators handle both non-organic products and organic products and the latter are stored in storage facilities in which also other agricultural products or foodstuffs are stored:

(a) the organic products shall be kept separate from the other agricultural products and/or foodstuffs;

(b) every measure shall be taken to ensure identification of consignments and to avoid mixtures or exchanges with non-organic products;

(c) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before the storage of organic products; operators shall record these operations.

EC No 834/2007 Title IV – Labelling

Article 23 – Use of terms referring to organic production

1. For the purposes of this Regulation a product shall be regarded as bearing terms referring to the organic production method where, in the labelling, advertising material or commercial documents, such a product, its ingredients or feed materials are described in terms suggesting to the purchaser that the product, its ingredients or feed materials have been obtained in accordance with the rules laid down in this Regulation. In particular, the terms listed in the Annex, their derivatives or diminutives, such as 'bio' and 'eco', alone or combined, may be used throughout the Community and in any Community language for the labelling and advertising of products which satisfy the requirements set out under or pursuant to this Regulation.

In the labelling and advertising of live or unprocessed agricultural products terms referring to the organic production method may be used only where, in addition, all the ingredients of that product have also been produced in accordance with the requirements laid down in this Regulation.

2. The terms referred to in paragraph 1 shall not be used anywhere in the Community and in any Community language for the labelling, advertising and commercial documents of a product which does not satisfy the requirements set out under this Regulation, unless they are not applied to agricultural products in food or feed or clearly have no connection with organic production. Furthermore, any terms, including terms used in trademarks, or practices used in labelling or advertising liable to mislead the consumer or user by suggesting that a product or its ingredients satisfy the requirements set out under this Regulation shall not be used.

3. The terms referred to in paragraph 1 shall not be used for a product for which it has to be indicated in the labelling or advertising that it contains GMOs, consists of GMOs or is produced from GMOs according to Community provisions.

4. As regards processed food, the terms referred to in paragraph 1 may be used:

(a) in the sales description, provided that:

(i) the processed food complies with Article 19;



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(ii) at least 95 % by weight, of its ingredients of agricultural origin are organic;

(b) only in the list of ingredients, provided that the food complies with Article 19(1), 19(2)(a), 19(2)(b) and 19(2)(d);

(c) in the list of ingredients and in the same visual field as the sales description, provided that:

(i) the main ingredient is a product of hunting or fishing;

(ii) it contains other ingredients of agricultural origin that are all organic;

(iii) the food complies with Article 19(1), 19(2)(a), 19(2)(b) and 19(2)(d).

The list of ingredients shall indicate which ingredients are organic.

In the case where points (b) and (c) of this paragraph apply, the references to the organic production method may only appear in relation to the organic ingredients and the list of ingredients shall include an indication of the total percentage of organic ingredients in proportion to the total quantity of ingredients of agricultural origin.

The terms and the indication of percentage referred to in the previous subparagraph shall appear in the same colour, identical size and style of lettering as the other indications in the list of ingredients.

EC 889/2008

Article 59 Scope, use of trade marks and sales descriptions: This Chapter shall not apply to pet food and feed for fur animals.

Key Comment 31

Under the NOP, pet food may not be certified under the livestock feed or livestock labeling requirements. The livestock definition does not include dogs, cats, or other pets. Pet food must be certified to the same standards as raw or processed agricultural products (205.301(a-d)).

Pet food and feed for fur animals cannot be certified to the EU standards as a whole and must not use the EU logo(s). However, EC 889 Article 95 states, "Pending the inclusion of detailed processing rules for pet food, national rules or in the absence thereof, private standards accepted or recognised by the Member States shall apply."

The trade marks and sales descriptions bearing an indication referred to in EC No 834/2007 Article 23(1) may be used only if at least 95 % of the product's dry matter is comprised of feed material from the organic production method.

Article 60 Indications on processed feed:

1. Without prejudice to Articles 61 and 59, second paragraph of this Regulation, the terms referred to in EC No 834/2007 Article 23(1) may be used on processed feed provided that:

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(a) the processed feed complies with the provisions of EC No 834/2007 and in particular with Article 14(1)(d)(iv) and (v) for livestock or with Article 15(1)(d) for aquaculture animals and Article 18 thereof;

(b) the processed feed complies with the provisions of this Regulation and in particular with Articles 22 and 26 thereof;

(c) at least 95 % of the product's dry matter is organic.

2. Subject to the requirements laid down in points (a) and (b) of paragraph 1, the following statement is permitted in the case of products comprising variable quantities of feed materials from the organic production method and/or feed materials from products in conversion to organic farming and/or non-organic materials: 'may be used in organic production in accordance with Regulations (EC) 834/2007 and (EC) 889/2008'

Article 61 Conditions for the use of indications on processed feed:

1. The indication provided for in Article 60 shall be:

(a) separate from the wording referred to in Article 5 of Council Directive 79/373/EEC or in Article 5(1) of Council Directive 96/25/EC;

(b) presented in a colour, format or character font that does not draw more attention to it than to the description or name of the animal feedingstuff referred to in Article 5(1)(a) of Directive 79/373/EEC or in Article 5(1)(b) of Directive 96/25/EC respectively;

(c) accompanied, in the same field of vision, by an indication by weight of dry matter referring:

(i) to the percentage of feed material(s) from the organic production method;

(ii) to the percentage of feed material(s) from products in conversion to organic farming;

(iii) to the percentage of feed material(s) not covered by points (i) and (ii);

(iv) to the total percentage of animal feed of agricultural origin;

(d) accompanied by a list of names of feed materials from the organic production method;

(e) accompanied by a list of names of feed materials from products in conversion to organic production.

2. The indication provided for in Article 60 may be also accompanied by a reference to the requirement to use the feedingstuffs in accordance with Articles 21 and 22.

From Directive 79/373/EEC, Article 5:

1. Member States shall prescribe that compound feedingstuffs may be marketed only if the particulars listed below, which shall be clearly visible, legible and indelible and for which the producer, packer, importer, seller or distributer established within the Community shall be held responsible, are set out in the package or



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Article 23 – Use of terms referring to organic production

container or on a label attached thereto:

(a) the description "compound feedingstuff";

(b) the species or category of animal for which the compound feedingstuff is intended;

(c) the purpose for which the feedingstuff is intended;

(d) directions for use if this is not clear from the particulars referred to in (b) or (c);

(e) the declarations listed in section 5 of the Annex;

Section 5 of the Annex 5. Declarations according to Article 5 (1):

5.1. Contents as regards analytical constituents of compound feedingstuffs, with the exception of whole grain mixes, compound feedingstuffs listed in 5.2 and 5.3:

crude protein / crude oils and fats / crude fibre / crude ash

5.2. Contents as regards analytical constituents of mineral feedingstuffs:

crude ash / calcium / phosphorus / sodium

5.3. Contents as regards analytical constituents of molassed feedingstuffs:

crude fibre / total sugar expressed as sucrose.

(f) the name or trade name and the address or registered office of the person responsible for the particulars referred to in this paragraph;

(g) the net weight; in the case of liquid products, the net volume or net weight.

In the case of compound feedingstuffs constituted from no more than three ingredients, the particulars referred to in (b) and, where appropriate, (c) and (d) shall not be required if the ingredients used appear clearly in the description.

2. Member States shall prescribe that compound feedingstuffs marketed in tankers or similar vehicles or in accordance with Article 4 (2) shall be accompanied by a document containing the particulars referred to in paragraph 1. For small quantities of feedingstuffs intended for the final user, these particulars may be brought to the purchaser's attention by means of an appropriate notice.

3. Member States may prescribe that the particulars listed in paragraph 1 (b) to (e) and (g) may be shown in an accompanying document only.

4. Member States may require all or some of the following particulars only to be indicated:

(a) the type of compound feedingstuffs, where appropriate, instead of the description "compound feedingstuff"; (b) the ingredients;

(c) the declarations provided for in sections 3. 4 and 6 of the Annex:



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Sections 3, 4 and 6 of the Annex:

3. The moisture content shall not exceed:

—in mineral feedingstuffs containing no organic substances: 5.0 %

-in mineral feedingstuffs containing organic substances: 10.0 %/

-in all other compound feedingstuffs except:

—whole grain

-molassed feeds

—semi-dry, moist and liquid compound feedingstuffs, it being understood that this moisture content level may be exceeded where preservatives have been used and provided that the moisture content and life of the feedingstuff are declared: 14.0 %.

4. Member States may, without prejudice to Article 3, prescribe that the level of ash insoluble in hydrochloric acid shall not exceed 3.3 % of the dry matter in the case of compound feedingstuffs composed mainly of rice by-products, and 2.2 % of the dry matter in other cases.

However, this level may be exceeded in the case of:

- compound feedingstuffs containing authorized mineral binding agents,

- mineral compound feedingstuffs, and

- compound feedingstuffs containing more than 50 % of sugar beet chips or pulp, provided that the level is declared as a percentage of the feedingstuff as such if it exceeds 33 % of the dry matter.

6. Declarations according to Article 5 (4):

6.1. Contents as regards analytical constituents and criteria for compound feedingstuffs, with the exception of whole grain mixes, compound feedingstuffs listed in 6.2, 6.3 and 6.4:

soluble protein / moisture / starch / total sugar expressed as sucrose / calcium / magnesium / sodium / phosphorus / cystine (Only for pigs, poultry and pre-ruminating ruminants) lysine / methionine / energy value calculated according to an officially recognized method.

6.2. Contents as regards analytical constituents of mineral feedingstuffs:

crude protein / soluble protein / crude oils and fats / crude fibre / magnesium / moisture / lysine (only for pigs).

6.3. Contents as regards analytical constituents of molassed feedingstuffs:

crude protein / soluble protein / crude oils and fats / crude ash / moisture.

(d) the date of manufacture;

(e) the net weight when (originally) packaged instead of the net weight laid down in 1 (g) above:



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(f) milk powder content for suckler feeds, and cereal content of compound feedingstuffs; in this case particulars of the other ingredients as required in Article 5 (7) shall not be necessary.

5. Member States shall prescribe that the following particulars only may be put on the package, container, label or accompanying document of compound feedingstuffs, in conjunction with the particulars listed in paragraph 1:

(a) the identification mark or trade mark of the person responsible for the particulars referred to in this paragraph;

(*b*) the batch number;

(c) the final date for keeping the product;

(*d*) the country of production or manufacture;

(e) the price of the product;

(f) directions for use, where not required by paragraph 1;

6. Member States may prescribe that the following particulars only may also be put on the package, container, label or accompanying document of compound feedingstuffs, in conjunction with the particulars listed in paragraph 1:

- (a) the name or trade name and the address or registered office of the manufacturer where the latter is not responsible for the labelling particulars;
- (b) the trade name of the product;

(c) the ingredients;

(e) the date of manufacture;

(f) the declarations listed in point 8 of the Annex.

point 8 of the Annex. Declarations according to Article 5 (6):

8.1. Contents as regards analytical constituents and criteria for compound feedingstuffs, with the exception of compound feedingstuffs listed in 8.2:

Moisture / starch / total sugar expressed as sucrose / soluble protein / calcium / magnesium / sodium / phosphorus / cystine (Only for pigs, poultry and pre-ruminating ruminants) / lysine / methionine / energy value calculated according to an officially recognized method.

8.2. Contents as regards analytical constituents of mineral feedingstuffs:

crude protein / soluble protein / crude oils and fats / crude fibre / magnesium.

7. Where particulars of the ingredients are given, all the ingredients present shall be listed, either by giving the quantities of each ingredient or in descending order of their proportion in the compound feedingstuff. Member States may prescribe the use of one of these two forms of indication, but not both. Where no measures have been adopted pursuant to Article 10 (b), Member States may group ingredients together by category or maintain existing categories and permit particulars of ingredients to be replaced by those relating to categories.



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EC No 834/2007 Title IV – Labelling

Article 23 – Use of terms referring to organic production

8. Any other information appearing on packaging, containers, labels and accompanying documents shall be shown separately from the particulars referred to in paragraphs 1 to 7.

From Directive 96/25/EC Article5(1):

1. Member States shall prescribe that feed materials may not be put into circulation unless the particulars listed below, which must be properly visible, legible and indelible and for which the producer, packer, importer, seller or distributor, established within the Community, shall be held responsible, are shown on an accompanying document or where appropriate on the packaging, on the container or on a label attached thereto:

(a) the words 'feed material';

(b) the name of the feed material;

(c) for feed materials listed in Part B of the Annex, the particulars provided for in the fourth column of Part B of the Annex;

(d) for feed materials which are not listed in Part B of the Annex, the particulars provided for in the second column of the table in Part C of the Annex;

(e) where appropriate, the particulars provided for in Part A of the Annex;

(f) the net quantity expressed in units of mass in the case of solid products, and in units of mass or volume in the case of liquid products;

(g) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph.

Key Comment 32

NOP only allows the terms "100% Organic," "Organic," and "Made with Organic."

Products labeled for the EU cannot use the terms "100% Organic," or "Made with Organic."

EU & NOP product calculation methods are slightly different. NOP requires <u>all ingredients</u> (other than salt and water) in the formulation to be used in the calculation.

Important: EU excludes not only salt and water but also non-agricultural food additives from the calculations. Although in most cases the difference in the calculations would be small, it is important to verify that the calculations were properly conducted by the certification body and the certified operation for each standard separately. It is possible to meet EU regulations but be in non-compliance with NOP.

Part A – C of Annex to Directive 96/25/EC added as attachment.



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EC No 834/2007 Title IV – Labelling

Article 24 – Compulsory indications

1. Where terms as referred to in Article 23(1) are used:

(a) the code number referred to in Article 27(10) of the certification body to which the operator who has carried out the most recent production or preparation operation is subject, shall also appear in the labelling;

(b) the Community logo referred to in Article 25(1) as regards pre-packaged food shall also appear on the packaging;

(c) where the Community logo is used, an indication of the place where the agricultural raw materials of which the product is composed have been farmed, shall also appear in the same visual field as the logo and shall take one of the following forms, as appropriate:

-'EU Agriculture', where the agricultural raw material has been farmed in the EU.

-'non-EU Agriculture', where the agricultural raw material has been farmed in third countries,

-'EU/non-EU Agriculture', where part of the agricultural raw materials has been farmed in the Community and a part of it has been farmed in a third country.

The abovementioned indication 'EU' or 'non-EU' may be replaced or supplemented by a country in the case where all agricultural raw materials of which the product is composed have been farmed in that country.

For the abovementioned 'EU' or 'non-EU' indication, small quantities by weight of ingredients may be disregarded provided that the total quantity of the disregarded ingredients does not exceed 2 % of the total quantity by weight of raw materials of agricultural origin.

The abovementioned 'EU' or 'non-EU' indication shall not appear in a colour, size and style of lettering more prominent than the sales description of the product.

The use of the Community logo as referred to in Article 25(1) and the indication referred to in the first subparagraph shall be optional for products imported from third countries. However, where the Community logo as referred to in Article 25(1) appears in the labelling, the indication referred to in the first subparagraph shall also appear in the labelling.

EC 889/2008

Article 58 Conditions for the use of the code number and place of origin: 1. The indication of the code number of the certification body referred to in EC No 834/2007 Article 24(1)(a)shall.

(a) start with the acronym identifying the Member State or the third country, as referred to in the international standard for the two letter country codes under ISO 3166 (Codes for the representation of names of countries and their subdivisions); (for the United States the ISO country code is of course "US")

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Article 24 – Compulsory indications

* (b) include a term which establishes a link with the organic production method, as referred to in EC No 834/2007 Article 23(1) in accordance with Part B(2) of Annex XI to this Regulation;

* (c) include a reference number to be decided by the Commission or by the competent authority of the Member States in accordance with Part B(3) of Annex XI to this Regulation; and

* (d) be placed in the same visual field as the Organic logo of the EU, where the Organic logo of the EU is used in the labelling.';

2. The indication of the place where the agricultural raw materials of which the products is composed have been farmed, as referred to in EC No 834/2007 Article 24(1)(c), shall be placed immediately below the code number referred to in paragraph 1.

*Amended by Article 1, paragraph 2 of EC No 271/2010. (Annex XI is in reference to the Annex contained in EC No 271/2010)

2. The indications referred to in paragraph 1 shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.

EC No 834/2007 **Title IV – Labelling**

Article 25 – Organic production logos

1. The Community organic production logo may be used in the labelling, presentation and advertising of products which satisfy the requirements set out under this Regulation. The Community logo shall not be used in the case of in-conversion products and food as referred to in Article 23(4)(b) and (c).

2. National and private logos may be used in the labelling, presentation and advertising of products which satisfy the requirements set out under this Regulation.

EC 889/2008

*Article 57 Organic logo of the EU:

The organic production logo of the European Union (hereinafter "Organic logo of the EU") shall follow the model set out in Part A of Annex XI to this Regulation.

The Organic logo of the EU shall only be used if the product concerned is produced in accordance with the requirements of Regulation (EEC) No 2092/91 and its implementing regulations or Regulation (EC) No 834/2007 and the requirements of this Regulation.';

*Amended by Article 1, paragraph 1 of EC No 271/2010. (Annex XI is in reference to the Annex contained in EC No 271/2010)

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EC No 834/2007 Title IV – Labelling

Article 26 – Specific labelling requirements

The Commission shall establish specific labelling and composition requirements applicable to:

(a) organic feed;

(b) in-conversion products of plant origin;

(c) vegetative propagating material and seeds for cultivation.

EC 889/2008

Article 62 In-conversion products of plant origin:

In-conversion products of plant origin may bear the indication 'product under conversion to organic farming' provided that:

(a) a conversion period of at least 12 months before the harvest has been complied with;

(b) the indication shall appear in a colour, size and style of lettering which is not more prominent than the sales description of the product, the entire indication shall have the same size of letters;

(c) the product contains only one crop ingredient of agricultural origin;

(d) the indication is linked to the code number of the control body as referred to in EC No 834/2007 Article 27(10).

*Amended by Article 1, paragraph 1 of EC No 271/2010. (Annex XI is in reference to the Annex contained in EC No 271/2010)

EC No 834/2007 Title V – Controls

Article 27 – Control system

...11. Certification bodies shall give the GV Division access to their offices and facilities and provide any information and assistance deemed necessary by the competent authorities for the fulfilment of their obligations according to this Article.

12. The certification bodies shall ensure that at least the precautionary and control measures are applied to operators subject to their control...

14. The certification bodies shall maintain a list of the operators which were subject to their controls on 31



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Article 27 – Control system

December of the previous year. A summary report of the control activities carried out during the previous year shall also be maintained.

Key Comment 33

Article 27 outlines the controls that must be followed by the GV Division as the competent authority and by the certification body as the control body. Only the requirements of the control system that are the responsibility of the certification body are included above.

Paragraph 14 requires the certification body to transmit its list of operators and a summary report of its control activities during the previous year to the GV Division on an annual basis. However, the GV Division only requires that the list and summary report are maintained and provided to the GV Division upon request.

EC No 834/2007 **Title V – Controls**

Article 28 – Adherence to the control system

1. Any operator who produces, prepares, stores, or imports from a third country products in the meaning of Article 1(2) or who places such products on the market shall, prior to placing on the market of any products as organic or in conversion to organic:

(a) notify his activity to the certification body where the activity is carried out;

(b) submit his operation to a control system of a certification body to verify compliance with the production rules laid down in this Regulation.

This shall apply also to exporters who export products produced in compliance with the production rules laid down in this Regulation.

Where an operator contracts out any of the activities to a third party, that operator shall nonetheless be subject to the requirements referred to in points (a) and (b), and the subcontracted activities shall be subject to the control system....

5. The certification body shall keep an updated list containing the names and addresses of operators under their control. This list shall be made available to the interested parties.

EC 889/2008

Article 63 Control arrangements and undertaking by the operator: 1. When the control arrangements are first implemented, the operator shall draw up and subsequently maintain:

(a) a full description of the unit and/or premises and/or activity;

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(b) all the practical measures to be taken at the level of the unit and/or premises and/or activity to ensure compliance with the organic production rules:

(c) the precautionary measures to be taken in order to reduce the risk of contamination by unauthorized products or substances and the cleaning measures to be taken in storage places and throughout the operator's production chain.

Where appropriate, the description and measures provided for in the first subparagraph may be part of a quality system as set up by the operator.

Key Comment 34

Key difference: If the operators have submitted an OSP that meets the requirements of the NOP then the requirements of this section will be met as long as the OSP includes information on "the cleaning measures to be taken in storage places and throughout the operator's production chain." While most ACA's require information on cleaning practices the EU Regulations specifically require it.

The EU does not require information to be submitted prior to the inspection.

2. The description and the measures referred to in paragraph 1 shall be contained in a declaration, signed by the responsible operator. In addition, this declaration shall include an undertaking by the operator:

(a) to perform the operations in accordance with the organic production rules;

(b) to accept, in the event of infringement or irregularities, the enforcement of the measures of the organic production rules;

(c) to undertake to inform in writing the buyers of the product in order to ensure that the indications referring to the organic production method are removed from this production.

The declaration provided for in the first subparagraph shall be verified by the certification body that issues a report identifying the possible deficiencies and non-compliances with the organic production rules. The operator shall countersign this report and take the necessary corrective measures.

3. The operator shall notify the following information to the certification body:

(a) Name and address of operator;

(b) Location of premises and, where appropriate, parcels (land register data) where operations are carried out;

(c) Nature of operations and products;

(d) Undertaking by the operator to carry out the operation in accordance with the provision laid down in Regulation (EC) No 834/2007 and this Regulation:



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(e) In the case of an agricultural holding, the date on which the producer ceased to apply products not authorised for organic production on the parcels concerned:

Article 64 Modification of control arrangements:

The operator responsible shall notify any change in the description or of the measures referred to in Article 63 and in the initial control arrangements set out in Articles 70, 74, 80, 82, 86 and 88 to the certification body in due time.

Article 65 Control visits:

1. The certification body shall carry out at least once a year a physical inspection of all operators.

2. The certification body may take samples for testing of products not authorised for organic production or for checking production techniques not in conformity with the organic production rules. Samples may also be taken and analysed for detecting possible contamination by products not authorised for organic production. However, such analysis shall be carried out where the use of products not authorised for organic production is suspected.

3. A control report shall be drawn up after each visit, countersigned by the operator of the unit or his representative.

4. Moreover, the certification body shall carry out random control visits, primarily unannounced, based on the general evaluation of the risk of non-compliance with the organic production rules, taking into account at least the results of previous controls, the quantity of products concerned and the risk for exchange of products.

Key Comment 35

Key difference: Paragraph 2 specifically <u>requires</u> certification bodies to collect samples for analysis where the certification body suspects the use of prohibited substances while the NOP states certifying agent's "may" test when they suspect the use of prohibited substances.

Key difference: Paragraph 4 specifically requires random unannounced control visits to be conducted by the certification body based on risk factors while the NOP states certifying agent's may conduct unannounced inspections but does not require them.

Important: EC 834/2007 preamble item 31 requires that operators submit to a control system setup and managed in conformity with EC 882/2004. EC 882/2004 was subsequently amended by EC 1029/2008. As amended EC 882/2004 Article 12 requires that samples are submitted only to those laboratories which have been accredited in accordance with EN ISO/TEC 17025 and/or EN ISO/TEC 17011.

Important:

To meet this requirement certification bodies have two options:

- 1) Ensure laboratories which are listed for testing (as required by ISO Guide 65 section 4.5.3 j) are accredited to EN ISO/TEC 17025 and EN ISO/TEC 17011; or
- 2) Ensure laboratories which are listed for testing meet the requirements of NOP 2611, NOP 2611 states laboratories should be accredited to EN ISO/TEC 17025 and also contains



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additional requirements. Thus if they meet the NOP requirements this would be considered equivalent to the EU standards.

Article 66 Documentary accounts:

1. Stock and financial records shall be kept in the unit or premises and shall enable the operator to identify and the certification body to verify:

(a) the supplier and, where different, the seller, or the exporter of the products;

(b) the nature and the quantities of organic products delivered to the unit and, where relevant, of all materials bought and the use of such materials, and, where relevant, the composition of the compound feedingstuffs;

(c) the nature and the quantities of organic products held in storage at the premises;

(d) the nature, the quantities and the consignees and, where different, the buyers, other than the final consumers, of any products which have left the unit or the first consignee's premises or storage facilities;

(e) in case of operators who do not store or physically handle such organic products, the nature and the quantities of organic products bought and sold, and the suppliers, and where different, the sellers or the exporters and the buyers, and where different, the consignees.

2. The documentary accounts shall also comprise the results of the verification at reception of organic products and any other information required by the certification body for the purpose of proper control. The data in the accounts shall be documented with appropriate justification documents. The accounts shall demonstrate the balance between the input and the output.

3. Where an operator runs several production units in the same area, the units for non organic products, together with storage premises for input products must also be subject to the minimum control requirements.

Article 67 Access to facilities:

1. The operator shall:

(a) give the certification body, for control purposes, access to all parts of the unit and all premises, as well as to the accounts and relevant supporting documents;

(b) provide the certification body with any information reasonably necessary for the purposes of the control;

(c) submit, when requested by the certification body, the results of its own quality assurance programmes.

2. In addition to the requirements set out in paragraph 1, importers and first consignees shall submit the information on imported consignments referred to in Article 84.



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CHAPTER 2 Specific control requirements for plants and plant products from farm production or collection

Article 70 Control arrangements:

1. The full description of the unit referred to in Article 63(1)(a) shall:

(a) be drawn up even where the operator limits his activity to the collection of wild plants;

(b) indicate the storage and production premises and land parcels and/or collection areas and, where applicable, premises where certain processing and/or packaging operations take place; and

(c) specify the date of the last application on the parcels and/or collection areas concerned of products, the use of which is not compatible with the organic production rules.

2. In case of collection of wild plants, the practical measures referred to in Article 63(1)(b) shall include any guarantees given by third parties which the operator can provide to ensure that the provisions of EC No 834/2007 Article 12(2) are complied with.

Article 71 Communications:

Each year, before the date indicated by the certification body, the operator shall notify the certification body of its schedule of production of crop products, giving a breakdown by parcel.

Article 72 Plant production records:

Plant production records shall be compiled in the form of a register and kept available to the certification body at all times at the premises of the holding. In addition to Article 71 such records shall provide at least the following information:

(a) as regards the use of fertiliser: date of application, type and amount of fertiliser, parcels concerned; (b) as regards the use of plant protection products: reason and date of treatment, type of product, method of treatment:

(c) as regards purchase of farm inputs: date, type and amount of purchased product;

(d) as regards harvest: date, type and amount of organic or in conversion crop production.

Article 73 Several production units run by the same operator states:

Where an operator runs several production units in the same area, the units producing non-organic crops, together with storage premises for farm input products shall also be subject to the general and the specific control requirements laid down in Chapter 1 and this Chapter of this Title.

CHAPTER 2a Specific control requirements for seaweed

Article 73a Control arrangements for seaweed:

When the control system applying specifically to seaweed is first implemented, the full description of the site referred to in Article 63(1)(a) shall include:



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(a) a full description of the installations on land and at sea;

(b) the environmental assessment as outlined in Article 6b(3) where applicable;

(c) the sustainable management plan as outlined in Article 6b(4) where applicable;

(d) for wild seaweed a full description and a map of shore and sea collection areas and land areas where post collection activities take place shall be drawn up.

Article 73b Seaweed Production Records:

1. Seaweed production records shall be compiled in the form of a register by the operator and kept available for the certification body at all times at the premises of the holding. It shall provide at least the following information:

(a) list of species, date and quantity harvested;

(b) date of application, type and amount of fertiliser used.

2. For collection of wild seaweeds the register shall also contain:

(a) history of harvesting activity for each species in named beds;

- (b) harvest estimate (volumes) per season;
- (c) sources of possible pollution for harvest beds;
- (d) sustainable annual yield for each bed.

CHAPTER 3 Control requirements for livestock and livestock products produced by animal husbandry

Article 74 Control arrangements:

1. When the control system applying specifically to livestock production is first implemented, the full description of the unit referred to in Article 63(1)(a) shall include:

(a) a full description of the livestock buildings, pasturage, open air areas, etc., and, where applicable, the premises for the storage, packaging and processing of livestock, livestock products, raw materials and inputs; (b) a full description of the installations for the storage of livestock manure.

2. The practical measures referred to in Article 63(1)(b) shall include:

(a) a plan for spreading manure agreed with the certification body, together with a full description of the areas given over to crop production;

(b) where appropriate, as regards the spreading of manure, the written arrangements with other holdings as referred to in Article 3(3) complying with the provisions of the organic production rules; (c) a management plan for the organic-production livestock unit.

Article 75 Identification of livestock:

The livestock shall be identified permanently using techniques adapted to each species, individually in the case of large mammals and individually or by batch in the case of poultry and small mammals.



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Article 76 Livestock records:

Livestock records shall be compiled in the form of a register and kept available to the certification body at all times at the premises of the holding. Such records shall provide a full description of the herd or flock management system comprising at least the following information:

(a) as regards animals arriving at the holding: origin and date of arrival, conversion period, identification mark and veterinary record;

(b) as regards livestock leaving the holding: age, number of heads, weight in case of slaughter, identification mark and destination;

(c) details of any animals lost and reasons thereof;

(d) as regards feed: type, including feed supplements, proportions of various ingredients of rations and periods of access to free-range areas, periods of transhumance where restrictions apply;

(e) as regards disease prevention and treatment and veterinary care: date of treatment, details of the diagnosis, the posology; type of treatment product, the indication of the active pharmacological substances involved method of treatment and veterinary prescription for veterinary care with reasons and withdrawal periods applying before livestock products can be marketed labelled as organic.

Article 77 Control measures on veterinary medicinal products for livestock:

Whenever veterinary medicinal products are used, the information according to Article 76(e) is to be declared to the certification body before the livestock or livestock products are marketed as organically produced.

Livestock treated shall be clearly identified, individually in the case of large animals; individually, or by batch, or by hive, in the case of poultry, small animals and bees.

Article 78 Specific control measures on beekeeping:

1. A map on an appropriate scale listing the location of hives shall be provided to the certification body by the beekeeper. Where no areas are identified in accordance with Article 13(2), the beekeeper shall provide the certification body with appropriate documentation and evidence, including suitable analyses if necessary, that the areas accessible to his colonies meet the conditions required in this Regulation.

2. Apiaries shall compile the following information in the form of a register regarding feed: including type of product, dates, quantities and hives where it is used.

3. Whenever veterinary medicinal products are to be used, the type of product, including the indication of the active pharmacological substance, together with details of the diagnosis, the posology, the method of administration, the duration of the treatment and the legal withdrawal period shall be recorded clearly and declared to the certification body before the products are marketed as organically produced.

4. The zone where the apiary is situated shall include in the register together with the identification of the hives. The certification body shall be informed of the moving of apiaries.

5. Particular care shall be taken to ensure adequate extraction, processing and storage of beekeeping products. All the measures to comply with this requirement shall be recorded.



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6. The removals of the supers and the honey extraction operations shall be entered in the register of the apiary.

Article 79 Several production units run by the same operator:

Where an operator manages several production units, as provided for in Articles 17(1), 40 and 41, the units which produce non-organic livestock or non-organic livestock products shall also be subject to the control system as laid down in Chapter 1 and this Chapter of this Title.

CHAPTER 3a Specific control requirements for aquaculture animal production

Article 79a Control arrangements for aquaculture animal production:

When the control system applying specifically to aquaculture animal production is first implemented, the full description of the unit referred to in Article 63(1)(a) shall include:

(a) a full description of the installations on land and at sea:

(b) the environmental assessment as outlined in Article 6b(3) where applicable;

(c) the sustainable management plan as outlined in Article 6b(4) where applicable;

(d) in the case of molluscs a summary of the special chapter of the sustainable management plan as required by Article 25q(2).

Article 79b Aquaculture animal production records:

The following information shall be provided by the operator in the form of a register which shall be kept up to date and made available for the certification body at all times at the premises of the holding

(a) the origin, date of arrival and conversion period of animals arriving at the holding:

(b) the number of lots, the age, weight and destination of animals leaving the holding;

(c) records of escapes of fish;

(d) for fish the type and quantity of feed and in the case of carp and related species a documentary record of the use additional feed;

(e) veterinary treatments giving details of the purpose, date of application, method of application, type of product and withdrawal period;

(f) disease prevention measures giving details of fallowing, cleaning and water treatment.

Article 79c Specific control visits for bivalve mollusks:

For bivalve mollusc production inspection, visits shall take place before and during maximum biomass production.

Article 79d Several production units run by the same operator:

When an operator manages several production units as provided for in Articles 25c, the units which produce non-organic aquaculture animals shall also be subject to the control system as laid down in Chapter 1and this Chapter.



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CHAPTER 4 Control requirements for units for preparation of plant, seaweed, livestock and aquaculture animal products and foodstuffs composed thereof

Article 80 Control arrangements:

In the case of a unit involved in the preparation for its own account or for account of a third party, and including in particular units involved in packaging and/or re-packaging of such products or units involved in labeling and/or re-labelling of such products, the full description of the unit referred to in Article 63(1)(a) shall show the facilities used for the reception, the processing, packaging, labelling and storage of agricultural products before and after the operations concerning them, as well as the procedures for the transport of the products.

CHAPTER 5 Control requirements for imports of organic products from third countries

Key Comment 36

Chapter 5 is specific to the EU Community. The GV Division does not assess certification bodies against these requirements. As a result, this Chapter is not included within this document.

CHAPTER 6 Control requirements for units involved in the production, preparation or import of organic products and which have contracted out to third parties in part or in total the actual operations concerned

Article 86 Control arrangements:

With regard to the operations, which are contracted out to third parties, the full description of the unit referred to in Article 63(1)(a) shall include:

(a) a list of the subcontractors with a description of their activities and an indication of the control bodies or authorities to which they are subject;

(b) written agreement by the subcontractors that their holding will be subject to the control regime of Title V of Regulation (EC) No 834/2007;

(c) all the practical measures, including inter alia an appropriate system of documentary accounts, to be taken at the level of the unit to ensure that the products the operator places on the market can be traced to, as appropriate, their suppliers, sellers, consignees and buyers.

CHAPTER 7 Control requirements for units preparing feed

Article 87 Scope :

This Chapter applies to any unit involved in the preparation of products referred to in EC No 834/2007 Article 1(2)(c) on its own account or on behalf of a third party.

Article 88 Control arrangements:

1. The full description of the unit referred to in Article 63(1)(a) shall indicate:



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(a) the facilities used for the reception, preparation and storage of the products intended for animal feed before and after the operations concerning them;

(b) the facilities used for the storage of other products used to prepare feedingstuffs;

(c) the facilities used to store products for cleaning and disinfection;

(d) where necessary, the description of the compound feedingstuff that the operator intends to produce, in accordance with Article 5(1)(a) of Directive 79/373/EEC, and the livestock species or class for which the compound feedingstuff is intended;

(e) where necessary, the name of the feed materials that the operator intends to prepare.

2. The measures to be taken by operators, as referred to in Article 63(1)(b), to guarantee compliance with the organic production rules shall include the indications of measures referred to in Article 26.

3. The certification body shall use these measures to carry out a general evaluation of the risks attendant on each preparation unit and to draw up a control plan. This control plan shall provide for a minimum number of random samples depending on the potential risks.

Article 89 Documentary accounts:

For the purposes of proper control of the operations, the documentary accounts referred to in Article 66 shall include information on the origin, nature and quantities of feed materials, additives, sales and finished products.

Article 90 Control visits:

The control visit referred to in Article 65 shall comprise a full physical inspection of all premises. Moreover, the certification body shall make targeted visits based on a general evaluation of the potential risks of noncompliance with the organic production rules.

The certification body shall pay particular attention to the critical control points pointed out for the operator, with a view to establishing whether the surveillance and checking operations are carried out correctly. All the premises used by the operator for the conduct of his activities may be checked as frequently as the attendant risks warrant.

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Article 29 – Documentary evidence

1. The certification body referred to in Article 27(4) shall provide documentary evidence to any such operator who is subject to their controls and who in the sphere of his activities, meets the requirements laid down in this Regulation. The documentary evidence shall at least permit the identification of the operator and the type or range of products as well as the period of validity.



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Article 29 – Documentary evidence

2. The operator shall verify the documentary evidence of his suppliers.

Article 68 Documentary evidence:

The certification body shall use the model of the documentary evidence set out in Annex XII to this Regulation.

EC No 834/2007 **Title V – Controls**

Article 30 – Measures in case of infringements and irregularities

1. Where an irregularity is found as regards compliance with the requirements laid down in this Regulation, the certification body shall ensure that no reference to the organic production method is made in the labelling and advertising of the entire lot or production run affected by this irregularity, where this would be proportionate to the relevance of the requirement that has been violated and to the nature and particular circumstances of the irregular activities

Where a severe infringement or an infringement with prolonged effect is found, the certification body shall prohibit the operator concerned from marketing products which refer to the organic production method in the labelling and advertising for a period to be determined by the certification body.

2. Information on cases of irregularities or infringements affecting the organic status of a product shall be immediately communicated between the certification body, GV Division and Member States concerned and, where appropriate, to the Commission.

The level of communication shall depend on the severity and the extent of the irregularity or infringement found.

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Article 91 Measures in case of suspicion of infringements and irregularities:

1. Where an operator considers or suspects that a product which he has produced, prepared, imported or that he has received from another operator, is not in compliance with organic production rules, he shall initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product. He may only put it into processing or packaging or on the market after elimination of that doubt, unless it is placed on the market without indication referring to the organic production method. In case of such doubt, the operator shall immediately inform the certification body. The certification body may require that the product cannot be placed on the market with indications referring to the organic production method until it is satisfied, by the information received from the operator or from other sources, that the doubt has been eliminated.

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Article 30 – Measures in case of infringements and irregularities

2. Where a certification body has a substantiated suspicion that an operator intends to place on the market a product not in compliance with the organic production rules but bearing a reference to the organic production method, this certification body can require that the operator may provisionally not market the product with this reference for a time period to be set by that certification body. Before taking such a decision, the certification body shall allow the operator to comment. This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if the certification body is sure that the product does not fulfil the requirements of organic production. However, if the suspicion is not confirmed within the said time period, the decision referred to in the first subparagraph shall be cancelled not later than the expiry of that time period. The operator shall cooperate fully with the certification body in resolving the suspicion.

EC No 834/2007 **Title V – Controls**

Article 31 – Exchange of information

Upon a request duly justified by the necessity to guarantee that a product has been produced in accordance with this Regulation, the competent authorities, control authorities and the control bodies shall exchange relevant information on the results of their controls with other competent authorities, control authorities and control bodies. They may also exchange such information on their own initiative.

EC No 834/2007 **Title VI – TRADE WITH THIRD COUNTRIES**

Article 32 – Import of compliant products Article 33 – Import of products providing equivalent guarantees

Key Comment 37

The rules outlined in Articles 32 and 33 are overseen by the EU Commission and importers who are importing organic product from a third country. The GV Division does not assess certification bodies against these requirements. As a result, these Articles are not included within this document.

It is important to note that products certified by certification bodies accredited under the USDA ISO Guide 65 Program are imported in accordance with Article 33(3). Products can not be imported in accordance with Article 33(2) as the Commission has not recognized the US as a third country whose system of production complies with the principles and production rules equivalent the EU regulations.



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EC No 834/2007 Title VII – Final and Transitional Rules

Article 34 – Free movement of organic products Article 35 – Transmission of information to the Commission Article 36 – Statistical information Article 37 – Committee on organic production Article 38 – Implementing rules Article 39 – Repeal of Regulation (EEC) No 2092/91 Article 40 – Transitional measures Article 41 – Report to the Council Article 42 – Entry into force and application

Key Comment 38

The GV Division does not assess certification bodies against the rules outlined in Articles 34-42. As a result, these Articles are not included within this document.

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Annex I – Annex XIIIa

Key Comment – Annex I

Items included in Annex I are also included on the NOP National List with the following exceptions:

Basic slag – No direct reference.

Stillage and stillage extract - Refer to §205.203(d)(5).

Magnesium sulphate (kieserite) – Refer to \$205.601(j)(5).

Calcium chloride solution – Refer to §205.602(c).

Industrial lime from sugar production - No direct reference.

Industrial lime from vacuum salt production – No direct reference.

Trace elements – Refer to \$205.601(j)(6).

Key Comment – Annex II

Items included in Annex II are also included on the NOP National List with the following exceptions:

Annex II.4:

Diammonium phosphate and Pyrethroids - No direct reference.

Annex II.5:

Ferric phosphate - Refer to §205.601(h).

Annex II.6:

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Copper in the form of copper hydroxide, copper oxychloride, (tribasic) copper sulphate, cuprous oxide, copper octanoate - Refer to (205.601(i)(1)) and (2).

Ethylene - Refer to §205.601(k) and §205.605(b).

Potassium aluminium (aluminium sulphate) (Kalinite) and Potassium permanganate - No direct reference.

Mineral Oils listed on Annex as insecticide and fungicide – No direct reference for this use.

Key Comment – Annex III

No direct reference within the NOP National List.

Key Comment – Annex IV

No direct reference within the NOP National List.

Key Comment – Annex V

Items included in Annex V are also included on the NOP National List with the following exceptions:

Sections 1.1 through 2.1 and 2.3: Refer to §205.237(a), §205.236(a)(2)(i), §205.603, and §205.604.

Section 2.2: Refer to §205.237(a).

Sections 3.1 through 3.6:

Refer to §205.603(d)(2). These products fall under trace minerals with the exception of "shells of aquatic animals" under section 3.3 which would be a non-synthetic (reference Section 2.2 comment above).

Key Comment – Annex VI

Items included in Annex VI are also included on the NOP National List with the following exceptions:

Section 1.1

Refer to §205.603(d)(2 & 3)

Section 1.2

Enzymes and Micro-organisms – No direct reference for this use



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Section 1.3(a) No direct reference for this use

Section 1.3(b) Refer to §205.605(b)

Section 1.3(c)

Calcium stearate of natural origin – No direct reference for this use Colloidal silica – No direct reference for this use Kieselgur (diatomaceous earth) – No direct reference for this use Kaolinitic clays – No direct reference for this use Natural mixtures of stearites and chlorite – No direct reference for this use Vermiculite – No direct reference for this use Sepiolite – No direct reference for this use Perlite – Refer to §205.605(a)

Section 1.3 (d), & 2 Refer to §205.237(a) & §205.605

Section 3 Refer to §205.237(a), §205.236(a)(2)(i), and §205.606(y).

Key Comment – Annex VII

Items included in Annex VII are also included on the NOP National List with the following exceptions:

Section 1

Potassium & Sodium Soap – No direct reference for this use Milk of lime – Refer to §205.603(b)(4) Lime – Refer to §205.603(b)(4) Quick Lime – Refer to §205.603(b)(4) Caustic soda – No direct reference for this use Caustic potash – No direct reference for this use Natural essences of plants – No direct reference for this use Citric, peracetic acid, formic, lactic, oxalic and acetic acids – Refer to §205.603(a)(19) Nitric Acid – No direct reference for this use Formaldehyde – No direct reference for this use Cleaning and disinfection products for teats and milking facilities – Refer to §205.603(a)(7) Sodium Carbonate – No direct reference for this use

Section 2

NOP does not have standards for aquaculture animals



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Key Comment – Annex VIII Part 1 Items included in Annex VIII are also included on the NOP National List with the following

Section A

exceptions.

Vegetable carbon – Refer to §205.605(b) Sodium metabisulphite – No direct reference for this use – Refer to §205.605(b) Potassium Metabisulphite – No direct reference for this use – Refer to §205.605(b) Sodium Nitriate – No direct reference for this use Potassium Nitrate – No direct reference for this use Sodium Ascorbate – No direct reference for this use Sodium lactate – No direct reference for this use Tocopherol-rich extract – Refer to §205.605(b) Tartaric acid – Refer to §205.605(b) Sodium Tartrates – No direct reference for this use Potassium tartrates – Refer to §205.605(b) Monocalcium phosphate – Refer to §205.605(b) Alginic acid – Refer to §205.605(b) (Alginates) Sodium Alginate – Refer to §205.605(b) (Alginates) Potassium Alginate – Refer to §205.605(b) (Alginates) Hydroxypropyl methyl cellulose – Refer to §205.605(b) Glycerol – No direct reference for this use Talc – No direct reference for this use Argon – No direct reference for this use Helium – No direct reference for this use Section B Calcium sulphate – Refer to \$205.605(a) (must be from a mined source)

Sulphuric acid – No direct reference for this use

Hydrochloric acid – No direct reference for this use Ammonium hydroxide – No direct reference for this use Ethanol – No direct reference for this use Tannic acid – No direct reference for this use Egg white albumen – Refer to \$205.605(b)Casein – No direct reference for this use Isinglass – No direct reference for this use Vegetable oils – No direct reference for this use Sodium Dioxide gel or colloidal solution – Refer to §205.605(b) Activated carbon – Refer to §205.605(b) Talc – No direct reference for this use Hazelnut shells - No direct reference for this use Rice meal – No direct reference for this use Beeswax – Refer to §205.605(b)



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Section C

Potato starch – Refer to §205.606(u) Vegetable oils – No direct reference for this use

NOTE: Many of the food additives, processing aids, and other products listed in Annex VIII have specific conditions for use under the EU regulations. It is important to verify that these specific conditions are met when the items are used for the production of EU organic food.

Key Comment – Annex IX

Items included in Annex IX are also included on the NOP National list with the following exceptions.

Section 1.1 No direct reference for this use for items listed

Section 1.2 Pepper (Peruvian) – No direct reference for this use Horseradish seeds – No direct reference for this use Lesser galangal – Refer to §205.606(i) Safflower flowers – No direct reference for this use

Watercress herb – No direct reference for this use

Section 1.3 Algae, including seaweed – Refer to §205.606(n) and (x)

Section 2.1 – Refer to §205.301(a-d)

Section 2.2

Fructose – No direct reference for this use Rice paper – No direct reference for this use Unleavened bread paper – No direct reference for this use Starch from rice and waxy maize, not chemically modified - Refer to §205.606(u)

Section 2.3

No direct reference for this use for the items listed

Section 3

Whey powder – Refer to §205.606(y)

Key Comment – Annex X

No direct reference within the NOP National List.

Key Comment – Annex XI

No direct reference within the NOP National List.



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Key Comment – Annex XII

No direct reference within the NOP National List.

Key Comment – Annex XIII

No direct reference within the NOP National List.

Key Comment – Annex XIIIa

No direct reference within the NOP National List.

Key Comments – National List

The following items are included on the NOP National List but are either not included in the Annexes or not listed for the same use in the Annexes.

§205.601 Synthetic substances allowed for use in organic crop production:

§205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems:

(1) Alcohol (Ethanol and Isopropanol) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems - Alcohol is listed twice on Annex VII for cleaning and disinfecting livestock buildings and installations and equipment and facilities in the absence of animals in an aquaculture operation but does not specifically include Ethanol and Isopropanol.

(2) Chlorine materials (Calcium hypochlorite, Chlorine dioxide, Sodium hypochlorite) ← Annex VII lists Calcium hypochlorite and Sodium hypochlorite but does not include Chlorine dioxide.

(7) Soap-based algicide/demossers \leftarrow No direct reference within the Annexes.

(8) Sodium carbonate peroxyhydrate (CAS #–15630–89–4) ← No direct reference within the Annexes.

§205.601(b) As herbicides, weed barriers, as applicable:

(1) Herbasides, soap-based

(2) Mulches

 \leftarrow No direct reference within the Annexes.

§205.601(c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks \leftarrow No direct reference within the Annexes.



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	(d) As animal repellents—Soaps, ammonium—for use as a large animal repellant only, no ith soil or edible portion of crop \leftarrow No direct reference within the Annexes.
205.601	e) As insecticides (including acaricides or mite control):
1) Ammo	onium carbonate
	us potassium silicate
(3) Boric	
	ose octanoate esters (CAS #s—42922–74–7; 58064–47–4) ect reference within the Annexes.
	cet reference within the Annexes.
	g) As rodenticides:
(1) Sulfur	
(2) Vitam	
← No dir	ect reference within the Annexes.
§205.601	i) As plant disease control:
	us potassium silicate (CAS #-1312-76-1)
· / •	gen peroxide
(8) Perace	
(11) Strep (12) Tetra	
	ect reference within the Annexes.
t ito un	
	(j) As plant or soil amendments
· · ·	sulfonate
	esium sulfate ins, B1, C, and E
	ous acid (CAS $\#$ 7782–99–2)
· /	ect reference within the Annexes other than Magnesium sulfate which has the stipulation
	st be of natural origin
8205 601	1) As floating agents in postharvest handling:
	sulfonate
(2) Sodiu	
	ect reference within the Annexes.
8205 601	m) As synthetic inert ingredients as classified by the Environmental Protection Agency
	r use with nonsynthetic substances or synthetic substances listed in this section and
· · · ·	n active pesticide ingredient in accordance with any limitations on the use of such
substance	· ·
(1) EPA I	
(2) EPA I	
\leftarrow No dir	ect reference within the Annexes.



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§205.601(n) Seed preparations. Hydrogen chloride (CAS # 7647–01–0)—for delinting cotton seed for planting \leftarrow No direct reference within the Annexes. §205.602 Nonsynthetic substances prohibited for use in organic crop production. (c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake \leftarrow Listed on Annex I with basically the same stipulation: "Calcium chloride solution – Foliar treatment of apple trees, after identification of deficit of calcium." §205.603 Synthetic substances allowed for use in organic livestock production. §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable: (2) Aspirin \leftarrow No direct reference within Annexes. (3) Atropine (CAS #-51-55-8) \leftarrow No direct reference within Annexes. (4) Biologics – Vaccines \leftarrow No direct reference within Annexes. (5) Butorphanol (CAS #-42408-82-2) \leftarrow No direct reference within Annexes. (6) Chlorhexidine ← Annex VII (1) – for cleaning and disinfection products for teats and milking facilities (8) Electrolytes – without antibiotics ← No direct reference within Annexes. (9) Flunixin (CAS# - 38677-85-9) \leftarrow No direct reference within Annexes. (10) Furosemide (CAS # - 54-31-9) \leftarrow No direct reference within Annexes. (11) Glucose ← Annexes VI (3) sugar & IX (2.2) (12) Glycerin ← Annex VII (1) – for cleaning and disinfection products for teats and milking facilities. (14) Iodine ← Annex VII (2) – Iodophores (15) Magnesium Hydroxide \leftarrow No direct reference within Annexes. (17) Oxytocin \leftarrow No direct reference within Annexes. (18) Paraciticides – Ivermectin \leftarrow No direct reference within Annexes. (21) Poloxalene (CAS # - 9003-11-6) \leftarrow No direct reference within Annexes. (22) Tolazoline (CAS # - 59 98-3) \leftarrow No direct reference within Annexes. (23) Xyalxine (CAS # - 7361-61-7) \leftarrow No direct reference within Annexes. \$205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable: (1) Copper Sulfate \leftarrow No direct reference within Annexes for this use. (3) Lidocaine \leftarrow No direct reference within Annexes. (5) Mineral oil \leftarrow No direct reference within Annexes. (6) Procaine \leftarrow No direct reference within Annexes. (7) Sucrose octanoate esters (CAS #s – 4922-74-7; 58064-47-4 ← No direct reference within Annexes. §205.603(c) As feed supplements: ← No direct reference within Annexes. Instructions: Save this Operational Guidance document for further reference. A controlled copy is located on the GV Division server at Procedures ARC Final.



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§205.603(d) As feed additives:

(1) DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #-59–51–8; 63–68–3; 348–67–4) \leftarrow No direct reference within Annexes.

§205.603(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsyntetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substance. (1) EPA List 4 \leftarrow No direct reference within the Annexes.

§205.603(f) Excipients: ← No direct reference within Annexes.

§205.604 Nonsynthetic substances prohibited for use in organic livestock production.

(a) Strychnine \leftarrow No direct reference within Annexes prohibiting the use of this item.

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(a) Nonsynthetics allowed:

Animal enzymes \leftarrow No direct reference within Annexes.

Dairy cultures: \leftarrow No direct reference within Annexes.

Enzymes: \leftarrow No direct reference within Annexes. Refer to EC No 889/2008 Article 27(1)(b).

Flavors: \leftarrow No direct reference within Annexes. Refer to EC No 889/2008 Article 27(1)(c).

Glucono delta lactone: \leftarrow No direct reference within Annexes

Magnesium sulfate: \leftarrow No direct reference within Annexes

Potassium chloride: \leftarrow No direct reference within Annexes

Potassium iodide: \leftarrow No direct reference within Annexes

(b) Synthetics allowed:

Calcium phosphates (dibasic and tribasic):
 Ko direct reference within Annexes

Chlorine materials (chlorine dioxide and sodium hypochlorite):

No direct reference within Annexes



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Cyclohexylamine: \leftarrow No direct reference within Annexes			
Diethylaminoethanol: \leftarrow No direct reference within Annexes			
Ethylene: \leftarrow No direct reference within Annexes for this use			
Ferrous Sulfate: ← No direct reference within Annexes. Refer to EC No 889/2008 Article 27(1)(f)			
Glycerides (mono and di): ← No direct reference within Annexes			
Magnesium stearate: \leftarrow No direct reference within Annexes			
Octadecylamine: \leftarrow No direct reference within Annexes			
Ozone: \leftarrow No direct reference within Annexes			
Peracetic acid/Peroxyacetic acid:			
Phosphoric acid: \leftarrow No direct reference within Annexes			
Potassium citrate: \leftarrow No direct reference within Annexes			
Potassium hydroxide: \leftarrow No direct reference within Annexes			
Potassium iodide: \leftarrow No direct reference within Annexes			
Potassium phosphate: \leftarrow No direct reference within Annexes			
Sodium acid pyrophosphate: \leftarrow No direct reference within Annexes			
Sodium phosphates: \leftarrow No direct reference within Annexes			
Tetrasodium pyrophosphate: \leftarrow No direct reference within Annexes			
§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."			
Celery powder: \leftarrow No direct reference within Annexes			
Chia: \leftarrow No direct reference within Annexes			
Colors derived from agricultural products \leftarrow With the exception of (1) Annatto, no direct reference within Annexes			
Dillweed oil: ← No direct reference within Annexes			



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Fish oil: \leftarrow No direct reference within Annexes	
Fortified cooking wines: \leftarrow No direct reference within Annexes	
Fructooligosaccharides: \leftarrow No direct reference within Annexes	
Hops: \leftarrow No direct reference within Annexes	
Inulin-oligofructose: \leftarrow No direct reference within Annexes	
Konjac flour: \leftarrow No direct reference within Annexes	
Lemongrass: \leftarrow No direct reference within Annexes	
Orange shellac-unbleached: \leftarrow No direct reference within Annexes	
Peppers (Chipoltle chilie): \leftarrow No direct reference within Annexes	
Sweet potato starch: \leftarrow No direct reference within Annexes	
Tragacanth gum: \leftarrow No direct reference within Annexes	
Turkish bay leaves: \leftarrow No direct reference within Annexes	
Wakame seaweed (<i>undaria pinnatifida</i>): ← No direct reference within Annexes	
Tragacanth gum: \leftarrow No direct reference within Annexes	