Section 11
Operational Requirements for Organic Processing Operations

11.0 Contents Page

This Section covers the operating procedures to be implemented by a registered organic processor.

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11.1 General Principles

11.1.01	These Standards apply to processing of organic products.
11.1.02	(Article 6 (834/2007)) In addition to the overall principles set out in Section 1, the production of processed organic food shall be based on the following specific principles: (a) The production of organic food from organic agricultural ingredients, except where an ingredient is not available on the market in organic form; (b) The restriction of the use of food additives, of non organic ingredients with mainly technological and sensory functions and of micronutrients and processing aids, so that they are used to a minimum extent and only in case of essential technological need or for particular nutritional purposes; (c) The exclusion of substances and processing methods that might be misleading regarding the true nature of the product; (d) The processing of food with care, preferably with the use of biological, mechanical and physical methods.
11.1.03	(Article 7 (834/2007)) (a) The production of organic feed from organic feed materials, except where a feed material is not available on the market in organic form; (b) The restriction of the use of feed additives and processing aids to a minimum extent and only in case of essential technological or zootechnical needs or for particular nutritional purposes; (c) The exclusion of substances and processing methods that might be misleading as to the true nature of the product; (d) The processing of feed with care, preferably with the use of biological, mechanical and physical methods.
11.1.04	(Article 18 (834/2007)) 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. 5. The measures and conditions necessary for the implementation of the production rules contained in this Article shall be adopted in accordance with the procedure referred to in Section 1.15.02.
11.1.05	(Article 19 (834/2007)) 1. The preparation of processed organic food shall be kept separate in time or space from non-organic food.

11.1.05 cont.	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 Section 11.1.07; (c) Non-organic agricultural ingredients may be used only if they have been authorised for use in organic production in accordance with Section 11.1.07 or have been provisionally authorised by a Member State; (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. The measures necessary for the implementation of the production rules contained in this Article, and in particular regarding processing methods and the conditions for the provisional authorisation by Member States mentioned in paragraph 2(c), shall be adopted in accordance with the procedure referred to in Section 1.15.02.
11.1.06	(Article 20 (834/2007)) 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 Section 11.1.07. 2. Organic yeast shall not be present in organic food or feed together with non-organic yeast. 3. Detailed production rules may be laid down in accordance with the procedure referred to in Section 1.15.02.
11.1.07	(Article 21 (834/2007)) 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 Section 11.1.05 (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; L 189/14 EN Official Journal of the European Union 20.7.2007 ii) Without having recourse to them, it would be impossible to produce or preserve the food or to fulfil given dietary requirements provided for on the basis of the Community legislation. In addition, the products and substances referred to in Section 11.1.05 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.

11.1.07 cont.	2. The Commission shall, in accordance with the procedure referred to in Section 1.15.02, 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. Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in this paragraph should be amended, the Member State shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the Member States. Requests for amendment or withdrawal, as well as decisions thereon, shall be published. Products and substances used before adoption of this Regulation and falling under Section 11.1.05 (2, b and c) may continue to be used after the said adoption. The Commission may, in any case, withdraw such products or substances in accordance with Section 1.15.02.

11.2 General Principles - Overview

OF&G Standards are based, as required by law, on the regulatory text of the Council Regulation EC 834/2007 and Commission Regulation EC 889/2008.

11.2.01

The OF&G Standards for organic processing ensure the organic integrity of the product throughout the processing operation.

The main requirements for organic processing operations are as follows:-

1. Statutory Legislation and Good Practice – organic regulations do not override statutory legislation, they are in addition to it. Each processing operation must be registered with the appropriate statutory authority (e.g. Defra, EHO, MHIS) and comply with all relevant statutory regulations and good practice;
2. Composition – non-organic ingredients and additives may be used as long as they are from the Approved Lists in Section 10. GMOs or ingredients derived from them are not allowed;
3. Organic status - there must be proof of organic status for all organic ingredients used;
4. Segregation and HACCP - organic ingredients must be clearly identified and segregated from non-organic products during:
   - Intake
   - Storage
   - Processing and Packing
   - Transport
   - Display in open packaging (sealed and labelled packaging does not need to be kept separate)

   A hazard analysis (HACCP) should be done to identify points in the process at which contamination may occur;
5. Cleaning - cleaning chemicals, procedures and standards should be appropriate to the industry. If wet cleans are done, they must be followed by a final water rinse to remove traces of any cleaning chemicals;
6. Pest Control - procedures should be appropriate to the industry and trained personnel used. Licensed rodent baits are permitted but spraying of any kind is strictly controlled;
7. Records for Traceability and Mass Balance – appropriate controls must be in place and adequate records kept, so that it is possible to trace all ingredients used, from intake through to the final products and to compare quantities of organic ingredients used with quantities of finished products made;

11.2.01 cont.	8. Training - staff must be trained to understand the organic requirements; 9. Processes – must be approved. Certain processes such as solvent extraction, or use of ionising radiation are not permitted; 10. Packaging – recyclable or biodegradable packaging is preferred where possible; 11. Labels and Marketing Literature – there are very specific labelling rules for organic products. All labels and marketing literature must be approved by OF&G at the proof stage. 12. Effluent Control – the operation should not have an adverse effect on the environment.

11.3 Statutory Legislation and Good Practice

11.3.01	Statutory Legislation. Organic regulations do not override other statutory legislation, they are in addition to it. Each organic processing operation must be registered with the appropriate statutory authority and comply with all relevant statutory regulations and codes of good practice. Inspection reports, recommendations, discharge licenses etc. from Statutory Authorities must be made available to OF&G if requested.
11.3.02	*The Food Safety Act 1990 applies to everyone involved in the processing, packing, preparation or sale of food. It is an offence to sell food that is injurious to health, unfit or contaminated.* *There are statutory requirements in regard to premises, equipment, the facilities that must be provided, general hygiene, composition, labelling and precautions that must be taken to protect food from contamination or deterioration.*
11.3.03	*Relevant statutory authorities include the following:* • *Food Processing: Environmental Health;* • *Abattoir or Meat Cutting: Meat Hygiene Inspection Service (MHIS);* • *Egg packing, animal feed processing, seed cleaning and packing, food or feed imports: DEFRA;* • *Most operations will have an annual inspection by Trading Standards to check scales, weighbridges, labelling etc.*
11.3.04	*Preparation establishments must conform to all relevant statutory requirements in regard to animal welfare, transport of livestock, premises, equipment, the facilities that must be provided, general hygiene and the precautions that must be taken to protect food from contamination or deterioration.* *Codes of practice on animal welfare, transport of livestock and hygiene, issued by either Defra or the Rural Affairs Departments in Scotland, Wales or Northern Ireland must be complied with.*
11.3.05	When requested by OF&G, the operator shall submit the results of its own voluntary inspection and sampling programmes.

Good Practice

11.3.06	(a) The site should be suitable for the enterprise; (b) The fabric and equipment at intake, processing, packing, storage and despatch areas should be fit for purpose and kept clean and in good condition so as not to contaminate the product; (c) The organisational structure should clearly define job descriptions, responsibilities and reporting relationships;

11.3.06 cont.	(d) Staff facilities, work wear and rules on personal hygiene should be appropriate so as to minimise the risk of product contamination; (e) Process controls (e.g. weight, temperature, time, foreign body) should be effective and measuring equipment should be calibrated to external standards; (f) Testing should be done to ensure product safety and conformity. Where external labs are used, they should be accredited by UKAS or equivalent; (g) Stock rotation procedures should ensure that ingredients are used in the correct order and within shelf-life; (h) Non-conforming products – procedures should be in place to ensure these are identified and quarantined then further treated as appropriate; (i) Product recall – a procedure should be in place and tested periodically, to ensure that all affected products can be identified and recovered; (j) Complaints – there should be a procedure to ensure these are documented, resolved and appropriate corrective action taken; (k) Visitors – site entry should be controlled to prevent the possibility of product contamination by outsiders.

11.4 Composition and Genetic Modification

Standards and Guidance Notes on the composition and labelling of organic products are given in Section 4.1. Information about permitted additives, processing aids and non-organic ingredients are given in Section 10 of this Manual. The notes below give a brief summary.	
11.4.01	(i) Ingredients (including additives) and processing aids may only be used in the production of organic products if they are organic or if they appear on the approved lists in this Manual; (ii) See Section 10 (Foods for Human Consumption), Section 8.4 (Animal Feed) and Section 7.7 (Seeds) for details of permitted non-organic ingredients, additives and processing aids; (iii) A Multi-Ingredient Product Sheet must be completed for each product with more than one ingredient. Record Sheet 42 (for food products) or 43 (for animal feed) may be used as proformas. Single ingredient products should be listed on Record Sheet 41. (Copies of these Record Sheets are in Section 14 of this Manual); (iv) These Record Sheets must be submitted to OF&G for approval before the products are marketed.
11.4.02	*In rare circumstances, it may be possible to obtain a derogation from Defra to use agricultural ingredients that are not on the permitted lists. (See Section 10.3).*
11.4.03	*Genetic Modification: Organic materials are, by definition, non-genetically modified (non-GM). A statement is required from suppliers of relevant non-organic agricultural products, additives and processing aids to confirm that they are not GM or GM-derivatives. (This applies particularly to maize, soya, rape, citric acid, enzymes, microbial products) This confirmation should be renewed at least annually.* *(OF&G Record Sheet 53 may be used.)* *See Sections 10.2 and 5.11 for further information on GMOs.*

11.5 Authentication of Organic Goods Received

11.5.01	Proof of organic status. Operators must keep a copy of each supplier's organic certificate (i.e. Certificate of Compliance to EC 834/2007 and EC 889/2008): (i) The certificate must be issued by an EC-approved organic control body, must be valid at the date the goods were supplied, must list the goods supplied and the trading name and address of the supplier; (ii) However, where small amounts of organic ingredients are bought retail, it may be impractical to demand a certificate. In this case the pack label and till receipt may be regarded as sufficient proof of organic status; (iii) If there is any doubt about the organic status of goods, they should not be further processed, packed or labelled as organic.
11.5.02	(Article 91 (889/2008)) 1) Where an operator considers or suspects that a product which he/she has produced, prepared, imported or had delivered from another operator, is not in compliance with this Manual, he/she shall initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product. He/she 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 control body or authority. The control body or authority 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. 2) Where a control body or authority has a substantiated suspicion that an operator intends to place on the market a product not in compliance with this Regulation but bearing a reference to the organic production method, this control body or authority can require that the operator may provisionally not market the product with this reference. This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if the control body or authority is sure that the product does not fulfil the requirements of organic production. However if the suspicion is not confirmed, the above decision shall be cancelled not later than the time period specified by the inspection body. The operator shall co-operate fully with the control body in resolving the suspicion.
11.5.03	Trading Standards Officers have the authority to enforce the above.

11.6 Segregation and HACCP

11.6.01	(i) Ideally the intake, storage, processing and packing areas should be dedicated to organic production; (ii) If not, there should be clear, well-understood written procedures to keep organic/certified products separate from non-organic products (including GM products and cleaning or pest control chemicals) throughout the process. There should be checklists to ensure procedures have been complied with. Organic integrity must be preserved at all times. Equipment must be clean. Containers, silos, packs etc. must be securely closed and clearly labelled; (iii) There should be a flow diagram to demonstrate the process and factory plan to show the layout.

11.6.02	(Article 26 (2) (889/2008)) HACCP: UK statutory legislation requires that all food and feed manufacturers carry out a hazard analysis of their process to determine whether there are any potential hazards to food safety. They must then set up a system to identify critical control points (points at which the hazard can be controlled) and monitoring systems to ensure this is done. This process is called a HACCP analysis (Hazard Analysis and Critical Control Points).
11.6.03	The application of the procedures referred to in Section 11.6.02 shall guarantee at all times that the produced processed products comply with the organic production rules.
11.6.04	(Article 26 (4) (889/2008)) Operators shall comply with and implement the procedures referred to in Section 11.6.02. 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.

Segregation during Goods Intake

11.6.05	*Effective records should be kept to record the origin, nature and quantity of organic products delivered to the unit.* *There should be proof of organic status for each item (see Section 11.4.01).*
11.6.06	*Intake checks:* *(i) Checks should be made that goods are securely packaged, labelled 'organic' and carry the symbol or code of the responsible control body. These checks should be recorded (OF&G Record Sheet 44 may be used);* *(ii) In the case of bulk deliveries, where there is no product packaging, the supplier's organic control body number should be on the delivery notes and/or invoice; e.g. for Organic Farmers & Growers the control body code is 'GB-ORG-02'.* *(iii) An intake procedure should be written and relevant staff trained to become familiar with organic labelling. (The UK control bodies are listed in Section 4.2.06 of this Manual). Details of control bodies from the UK, EU and Third Countries can be obtained from OF&G);* *(iv) All documentation (purchase orders, delivery notes, invoices as relevant) should state that the goods required are organic.*
11.6.07	(Article 33 (889/2008)) On receipt of a labelled organic product, the operator shall check the closing of the packaging or container where it is required and the presence of the indications referred to in Section 4.2 and Sections 11.6.18 and 11.6.19. The operator shall cross-check the information on the label with the information on the accompanying documents. The result of these verifications shall be explicitly mentioned in the documentary accounts referred to in Section 11.9.04.

Segregation during Storage

11.6.08	(Article 35 (889/2008)) All organic goods, whether raw materials, work-in-progress or finished products, must be stored so there is no possibility of them being contaminated in any way by conventional products or chemicals of any sort, including cleaning or pest control chemicals. Containers, including bulk bins, silos and pallets, should be closed securely and clearly labelled. Ideally these goods will be stored in designated areas or sealed securely and stretch-wrapped on pallets.
11.6.09	(Article 35 (889/2008)) For the storage of products, areas must be managed in order 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.

Segregation during Processing and Packing

11.6.10	*(i) Ideally, equipment should be dedicated to organic production. Where this is not so, to prevent contamination, processing of organic materials should take place as the first operation of the day or following a clean down or a bleed run;* *(ii) The simultaneous processing or packing of organic and non-organic products on the same line, is not permitted;* *(iii) Bleed Runs: if equipment cannot be taken apart for thorough cleaning before organic production starts and cleaning in place (CIP) is not possible, a suitable product must be passed through the equipment to purge it of any non-approved, GM or medicated material (this is called a bleed run). The operator needs to justify the type and amount of bleed material used. Material from bleed runs must not be returned to organic raw material stores or used in organic finished products;* *(iv) The operation should ideally be completed without interruption. Where this is not possible (e.g. meat brining, cheese maturing), the process must be carefully controlled to prevent contamination of the organic products;* (v) *In each case above, there should be written procedures and checklists to ensure the process is controlled and recorded.*
11.6.11	(Article 26 (5) (889/2008)) Where products not referred to in Section 4.1 *(i.e. non-organic products)* are also prepared, packaged or stored in the preparation unit concerned: (i) The unit must have areas separated by place or time within the premises for the storage of products as referred to in Section 4.1, before and after the operations; (ii) Operations must be carried out continuously until the complete run has been dealt with, separated by place or time from similar operations performed on products not covered by Section 4.1; (iii) If such operations are not carried out at regular times or on a fixed day, they must be announced in advance, with a deadline agreed on with OF&G; (iv) Every measure must be taken to ensure identification of lots and to avoid mixtures or exchanges with products not obtained in accordance with the rules laid down in this Manual; (v) Operations on products in accordance with the rules laid down in this Manual must be carried out only after cleaning of the production equipment. The effectiveness of the cleaning measures must be checked and recorded.

11.6.12	(Article 35 (4) (889/2008)) Where non-organically produced products are also processed, packaged or stored in the unit concerned: (i) Effective procedures and practices, supported by effective documented control systems and records, must be established and maintained to ensure that throughout the production cycle organically produced products are kept completely separate from non-organic products; (ii) Operations must be separated by time from similar operations performed on non-organic products. Prior to use for organic production the plant and equipment used, particularly product contact surfaces, must be effectively cleaned. The plant and equipment must be inspected prior to use to ensure that it is clean and free from residues that may contaminate or impair the organic integrity of the products.
11.6.13	*Approved materials for bleed runs are: potable water, organic products or products from the approved lists in Section 10 of this Manual (for food) or from Section 8 (for animal feed).* *For animal feed and seed mixes, it is often preferable to make sure the batch that goes through the plant before a batch of organic or approved feed or seeds, contains only approved ingredients, then there may be no need for a bleed run.*
11.6.14	*Contamination Checks: Carry-over checks should be in place to ensure there is no contamination from medicated products, GM-products, etc. There should be proof that these checks are effective.*
11.6.15	*Non-organically produced products may be processed, packaged or stored in the unit concerned subject to the provisions of Sections 11.6.10 to 11.6.14 being observed.*

Segregation during Transport

11.6.16	*(i) Fully wrapped materials may be transported in wagons cleaned to industry-standard without further conditions;* *(ii) Bulk wagons or containers must be thoroughly cleaned and checked before being loaded with organic products;* *(iii) For dry goods (e.g. grains) dry cleaning (brushing/vacuuming) may be adequate if the previous load was non-GM / non-medicated and not on the Agricultural Industries Confederation (AIC) Sensitive List (Ref: www.agindustries.org.uk);* *(iv) Otherwise wet cleans using detergents and/or steam should be done. (All cleaning chemicals should be rinsed off with potable water before organic goods are loaded);* *(v) Note: Wagons that have carried materials on the AIC Exclusion List (e.g. radioactive material) must not be used to transport organic products;* *(vi) Before organic products are loaded onto bulk wagons, details of the 3 previous loads should be checked to ensure they are not on the AIC Haulage Exclusion List, or, if they are on the AIC Sensitive List, that they have been appropriately cleaned;* *(vii) Wagons for un-wrapped chilled products (e.g. meat) should be cleaned using appropriate detergent / sanitiser then rinsed with potable water before loading;* *(viii) Accompanying documentation must clearly describe the goods and their organic status.*

11.6.17	(Article 30 (889/2008)) Milk, eggs and egg-products from organic farming shall be collected independently from products not produced in accordance with this Manual. Subject to the prior approval by the control body or authority, simultaneous collection may occur, where appropriate measures are taken to prevent any possible mixture or exchange with products not produced in accordance with this Regulation and to ensure the identification of the products produced in accordance with the provisions of this Manual. The operator must keep the information relating to collection days, hours, circuit and date and time of reception of the products available to the control body or authority.
11.6.18	(Article 31 (1) (889/2008)) The 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, including a reference to the organic production method, in accordance with Section 4.1; (c) The name and/or the code number of the control body or authority 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 control body or authority and which permits to link the lot with the accounts referred to in Section 11.9.
11.6.19	(Article 31 (1) (889/2008) cont.) The information under (a), (b), (c) and (d) above can also be presented on an accompanying document, if such document can be undeniably linked with the packaging, container or vehicle of the product. This accompanying document shall include information on the supplier and/or the transporter.
11.6.20	(Article 31 (2) (889/2008)) The closing of packaging, containers or vehicles is not required where: (i) Transportation is direct between a producer and another operator who are both subject to the inspection system referred to in Section 5; and (ii) The products are accompanied by a document giving the information required under the previous subparagraph; and (iii) Both the expediting and the receiving operators shall keep documentary records of such transport operations available for the control body or control authority of such transport operations.

11.7 Cleaning

11.7.01	The level of cleaning should comply with industry standards and should prevent microbial, chemical or foreign body contamination of the products. All product contact surfaces including utensils should be cleaned before organic production starts.

11.7.02	Chemicals: Industry-approved detergents and/or sanitisers may be used, however there **must be a final rinse with potable water** before production starts, to remove any trace of chemicals. (A disinfectant such as alcohol may be used only if 100% evaporation, leaving no residue, can be ensured).
11.7.03	Dry cleaning and bleed runs: Dry cleaning may be done where wet cleans are not practical. In cases where it is not possible to do dry or wet cleaning, a bleed run may be done, by passing a suitable product through the equipment to purge it of any non-approved, GM or medicated material.
11.7.04	Documentation: There must be clear, simple, written cleaning procedures and checklists. The checklists must be signed off when cleaning and final water rinses have been done. For dry cleans, the checklists must be signed off when the equipment has been cleaned and checked to make sure there are no residues left.
11.7.05	Water: Where chlorine levels are variable, it is acceptable to treat the water to ensure a consistent level. Where this is done, the residual level at point of use must be monitored on a daily basis and must never be above the WHO guideline of 1mg/litre. If borehole or well water is used, it must be treated, in accordance with statutory requirements, to ensure it is potable (safe for drinking). Levels of chlorine, if used, must be strictly monitored and residual levels must never be above 1mg/litre.
11.7.06	*Production establishments must conform to all relevant statutory requirements in regard to animal welfare, transport of livestock, premises, equipment, the facilities that must be provided, general hygiene and the precautions that must be taken to protect food from contamination or deterioration.*
11.7.07	Records must be kept of plant cleaning schedules including a list of all substances used.
11.7.08	*Whichever type of cleaning is done, checks should be carried out to make sure it is satisfactory (e.g. visual check, biotrace, swabs, carry-over tests).*
11.7.09	Fogging / Spraying: If cleaning / disinfection is done using foggers / sprayers, all organic materials (including packaging) must be removed from the area. Three times the normal dispersal time should be allowed, then all product contact surfaces rinsed with potable water before any organic materials are returned to the area.
11.7.10	Cleaning chemicals must be clearly labelled and stored safely to ensure they cannot contaminate products.
11.7.11	Product contact surfaces should be smooth, easy to clean, free from cracks and crevices and made from non-porous food grade materials that are inert to the food under conditions of use.
11.7.12	All product contact surfaces should be readily accessible for manual cleaning or if not then readily disassembled for manual cleaning. If clean-in-place methods are used it should be demonstrated that the results achieved are equivalent to those obtained by disassembly and manual cleaning.
11.7.13	The following substances are not permitted: (i) Substances that could taint or contaminate the product if used on contact surfaces; (ii) Persistent or carcinogenic disinfectants.

11.8 Pest Control

11.8.01	Good housekeeping, buying from good suppliers, checking incoming goods for infestation, keeping the fabric (walls/floors/doors) in good condition and use of fly screens etc. should reduce the need for pest control. If further pest control is needed, approved methods are wax block rodent baits (using licensed poisons), electric fly killers (EFKs), pheromone traps or sonic methods. There must be a plan of the site showing locations of bait stations etc. and these should be placed where there is no risk of contaminating product.
11.8.02	Sprays and fumigants are <u>not</u> approved for regular use because these can contaminate products/packaging. In special cases (e.g. infestation) spraying with approved chemicals <u>may</u> be done but all organic ingredients/products/packaging must be removed from the area, extra dispersal time allowed and all product contact surfaces rinsed with potable water before they are brought back. OF&G must be contacted before such a spraying programme commences. (See Sections 11.8.08 to 11.8.10).
11.8.03	If an external pest control contractor is used, the contractor should be a member of the British Pest Control Association or equivalent body and be made aware that the site is organic and that appropriate treatments should be used. The contractor should be asked to provide a letter confirming this, and this letter should be placed in the site pest control manual. If pest control is carried out in-house, the person should be trained to understand COSHH issues etc. There should be an appropriate bait plan, a safety data sheet for each chemical used and all treatments should be recorded. (A copy of OF&G Record Sheet 48 may be used). Only chemicals that are suitable for use in the food or feed industry (as appropriate) may be used.
11.8.04	*This guidance has been set out to achieve the following objectives:* *i) To emphasise the importance of prevention rather than cure;* *ii) To avoid contamination of organic food by any form of pests, be that infestation from micro-organisms, insects, rodents or other pests;* *iii) To ensure that organic foods are not affected by contamination from substances used to control pests;* *iv) To minimise environmental harm resulting from the control of pests.*
11.8.05	A preventive programme is the basis of effective pest control. The operator must therefore be able to demonstrate, including written records, that: (i) All storage and production premises, whether operator or third party controlled are managed as set out below; (ii) The design and construction of the premises are suitable for the prevention of pest and infection build up; (iii) Adequate control measures are taken to prevent imported pests. This should include raw materials via checks on incoming products, supplier audits and also on other risks, in particular second hand plant; (iv) Good stock rotation has been maintained; (v) The operator must be able to demonstrate that they have taken the necessary precautions to ensure that newly employed plant or premises are free from contamination by non-permitted materials; (vi) Potential entry points for pests are controlled, e.g. drains, door, windows, ventilation ducts are screened;

<table>
<tr><td>11.8.05 cont.</td><td colspan="2">(vii) The site is well managed, e.g. outside walls kept clear, spillage cleared and appropriate waste management practices in place;
(viii) There exists an effective cleaning program, clearly documented, thoroughly implemented and accurately recorded;
(ix) Regular monitoring and pest activity should be undertaken by a registered pest control contractor or suitably trained person and records kept.</td></tr>
<tr><td>11.8.06</td><td colspan="2">In the event that the preventative measures are not effective, the following requirements must be met:
(i) Exact records must be kept of all pest control measures taken;
(ii) Substances used for pest control must be correctly labelled and stored under lock and key when not in use;
(iii) Any measures using controlled substances must prevent direct contact with organic raw materials or product;
(iv) All treatments must be carried out by a suitably qualified person and in accordance with latest COSHH Regulations.</td></tr>
<tr><td>11.8.07</td><td colspan="2">Those parts of the site that are not used for organic production or storage, and which are under the control of the operator should be treated, where possible, using only methods permitted or restricted below.
Use of other methods must ensure the prevention of contamination of organic production or storage by migration, contact, personnel etc.
In cases where fumigation of premises, plant or equipment is required the treatment must be carried out in accordance with the COSHH Regulations. Adequate clearance time must be allowed for the fumigant to disperse and effective steps must be taken to ensure that fumigant residues do not remain on product contact surfaces before the premises, plant or equipment is used again for organic production. Organically produced raw materials, semi-finished or finished products must not be present when fumigation treatments are carried out.</td></tr>
<tr><td>11.8.08</td><td colspan="2">The following substances and processes are permitted:</td></tr>
<tr><td></td><td>Name</td><td>Description, compositional requirements, conditions for use</td></tr>
<tr><td></td><td>Freezing, heating and vacuum.
Carbon dioxide, nitrogen.</td><td>For treatment of products and packaging.</td></tr>
<tr><td></td><td>Ozone (gas)</td><td>Fumigation of food processing and storage premises, particularly against mould in dairies. Neither personnel nor organic products should be present during fumigation.</td></tr>
<tr><td></td><td>Mechanical barriers, sound and light, including UV.</td><td></td></tr>
<tr><td></td><td>Electrical insect killers.</td><td></td></tr>
<tr><td></td><td>Legally approved rodenticides or insecticides</td><td>Tamper evident bait stations containing legally approved rodenticides or insecticides in locations where there is no risk of contamination.</td></tr>
<tr><td></td><td>Pheromone traps and sticky boards not containing pesticides.</td><td>Where the latter are used for rodent control, they must be in accordance with British Pest Control Association Code of Practice.</td></tr>
<tr><td></td><td>Dessicant dust</td><td>Dessicant dusts (e.g. diatomaceous earth and amorphous silica) derived from naturally occurring sources and where there is no risk of contamination.</td></tr>
</table>

<table>
<tr><td>11.8.09</td><td colspan="2">The following materials may only be used under the conditions specified:</td></tr>
<tr><td></td><td>Name</td><td>Description, compositional requirements, conditions for use</td></tr>
<tr><td></td><td>Synthetic pyrethroids.</td><td>Only for:
(i) Enclosed and sealed units such as motor housings and wiring conduits;
(ii) Band applications around entrances and external apertures.</td></tr>
<tr><td>11.8.10</td><td>Pyrethrins, extracted from a natural botanical source and synergised using piperonyl butoxide (BPO) derived from a natural source e.g. oil and sassafras.</td><td>When using as a surface treatment, space spray or fog for insect control, any organic products or contact packaging must be removed or protected in such a way as to form an effective barrier to contact with the spraying agent.
The barrier is to remain in place for 24 hours after the spraying has taken place.
Adequate ventilation and cleaning of contact surfaces must take place after the 24 hour withdrawal period and prior to resumption of processing of organic food within the treated area.</td></tr>
<tr><td>11.8.11</td><td colspan="2">Permission to use restricted treatments should be sought in advance from OF&G. The application should detail reasons for use, substance and details of the procedures to avoid product contamination. In exceptional circumstances, treatment may be carried out and OF&G notified within two working days.</td></tr>
<tr><td>11.8.12</td><td colspan="2">Any control substances not listed as permitted or restricted for use in Sections 11.8.08 to 11.8.10, including organo-phosphates and known carcinogenic substances, are prohibited.</td></tr>
</table>

11.9 Records for Traceability and Mass Balance

<table>
<tr><td>11.9.01</td><td>(i) Records must be kept with full details of all raw materials bought in. These should include, as a minimum, type of ingredient, amount, supplier, date, batch number;
(ii) It must be possible to trace all ingredients used, from intake through to the final products and to compare quantities of organic ingredients used with quantities of finished products made (i e. do a mass balance);
(iii) Controls and records should be such that traceability of ingredients/products is not lost at any stage during the production/packing/despatch process;
(iv) These records should include material used for bleed runs, rework and work-in-progress where applicable. (OF&G Record Sheets may be used);
(v) A complete physical stocktake of the site should be done at least once per year.</td></tr>
<tr><td>11.9.02</td><td>To complete a mass balance calculation or reconciliation between inputs and outputs, the following information is normally required. It can be done over a day, a week or a month depending on the type of business:
(i) Quantities of raw materials in stock;
(ii) Quantities of raw material delivered;
(iii) Quantities of finished products made and their recipes;
(iv) Wastage (including bleed run material);
(v) Quantities of finished products sold;
(vi) Quantities of finished products remaining in stock.
OF&G Record Sheet 56 can be used for calculating a mass balance.</td></tr>
</table>

11.9.03	Examples of despatch records: (i) Wholesale transaction – copy of despatch/delivery note or sales invoice; (ii) Retail outlet – carbon copy from duplicate book or till record; (iii) Home delivery scheme (e.g. veg box) - copy of list of ingredients of standard veg boxes sent out each week plus details of special orders; (iv) Restaurant – daily menu, recipe sheets and record of numbers of each type of meal sold.
11.9.04	(Article 66 (1) (889/2008)) Stock and financial records shall be kept on the premises and shall enable the operator to identify, and OF&G 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.
11.9.05	(Article 66 (2 – 3) (889/2008)) The documentary accounts shall also comprise the results of the verification at reception of organic products and any other information required by the control authority or control 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. 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 subjected to the minimum control requirements.
11.9.06	(Article 67 - 68 (889/2008)) Processors must keep accurate records of their processing activities and make these available to OF&G. The records must be sufficiently comprehensive to allow the organic raw materials used in finished products to be traced back to the original source. The records must be retained for a period of not less than 3 years. Records should include: (i) The origin, nature and quantities of organically produced agricultural products which have been delivered to the unit; (ii) The origin, nature and quantities of non-organically produced agricultural products, non-agricultural ingredients and processing aids which have been delivered to the unit; (iii) The composition of the organically produced products; (iv) The nature, quantities and consignees of the organically produced products which have left the unit;

11.9.06 cont.	(v) Stock records for raw materials and finished products; (vi) Plant cleaning schedules including a list of all substances used; (vii) Details of any fumigation treatment of premises or equipment including dates of treatment, method of application, substances used, person or organisation responsible for the treatment, clearance time between completion of the treatment and the commencement of processing operations on organic products; (viii) Pest control records including a list of the substances used.

11.10 Training

11.10.01	All Staff whose activities may affect the integrity of the organic products (including goods-in, processing, packing and cleaning staff) must be trained so that they fully understand the organic procedures and comply with them. There must be records to show this training has taken place.
11.10.02	(i) A copy of this Manual must be on site and available for all staff with responsibility for organic processing operations; (ii) A simple procedure must be written by each operator to explain how the organic requirements (summarised at Section 11.2.01) apply to their process; (iii) The HACCP (see Section 11.6) must be taken into account when drawing this up; (iv) Staff must be trained to understand and comply with this procedure.

11.11 Non-Approved Processes

11.11.01	Certain processes such as ionising radiation, solvent extraction and hydrogenation of oils, are not allowed in organic processing.
11.11.02	(Article 10 (834/2007)) The product or its ingredients must not have been subject to treatments involving the use of ionising radiation.
11.11.03	Slow and ritual methods of livestock slaughter are not permitted.

11.12 Packaging

11.12.01	Packaging must be adequate to protect the product and be stored off the floor and away from walls, in clean, dry conditions. Packaging should be made of environmentally benign (i.e. biodegradable) materials and/or be returnable where practicable.
11.12.02	*As far as is reasonably practicable, biodegradable materials made from plant materials, e.g. starch-based plastic, should be used for the packaging of organic products.*
11.12.03	Materials used for product packaging must be of food grade quality, clean, unused and be strong enough to protect the product during handling, transit and as appropriate display. The packaging must not affect the organoleptic character of the product or transmit to it any substances in quantities that may be harmful to human health.
11.12.04	***Partnership Programme – PVC films free from plasticisers may only be used for non-fat foods.***

11.12.05	***Partnership Programme – Aluminium foils are not permitted when in direct contact with acidic foods (equal to or less than pH 4.5) or salty foods (in excess of 2%) unless the film has been lacquered.***
11.12.06	***Partnership Programme – Expanded polystyrene packaging made with CFCs is not permitted.***

11.13 Labelling and Marketing

The full Standards and Guidance Notes for the Labelling of Organic Products are given in Section 4 of this Manual. The notes below give a brief summary.	
11.13.01	A product label must clearly and accurately describe the product – it must not be misleading. It must also comply with all relevant legislation. UK law states that food products must be labelled with: (i) The name of the food; (ii) Declaration of quantity (weight or volume); (iii) A list of the ingredients in descending order; (iv) A 'use by' or 'best before date' (if this does not provide sufficient traceability, a batch code must also be used); (v) Usage or storage instructions; (vi) The name and contact details of the manufacturer, packer or seller.
11.13.02	**For organic products**, the following is also required: (i) The statement 'GB-ORG-XX' must be on the label of all food / feed products to identify the control body with which the producer/processor is registered. (For OF&G licensees, the code is GB-ORG-02); (ii) In the list of ingredients, the organic items must be clearly differentiated from those that are non-organic.
11.13.03	Use of the control body's logo is voluntary. However it is useful as a marketing aid and OF&G's logo includes the statement 'GB-ORG-02', and thus incorporates the requirement at Section 11.13.02 (i).

11.14 Effluent Control

11.14.01	*One of the basic principles of organic farming is the avoidance of pollution.* *(a) Organic processing enterprises must follow the same principle and develop procedures to minimise their impact on the environment;* *(b) Waste materials should be recycled or processed on site wherever possible to minimise their impact on the environment.*

11.15 Specific Provisions for Animal Feed Processors

11.15.01	(Article 87 (889/2008)) This Section applies to any unit involved in the preparation of animal feedingstuffs, compound feed and the feed materials on its own account or on behalf of a third party, where these products carry or are intended to carry references to the organic production method.

11.15.02	*The detailed requirements for the labelling of animal feeds are given in Section 4.3 and for the constituents of animal feeds in Section 8.4.*

Initial Inspection

11.15.03	(Article 88 (1) (889/2008)) The full description of the unit must: Indicate the facilities used for the reception, preparation and storage of the products intended for animal feed before and after the operations concerning them; (i) Indicate the facilities used for the storage of other products used to prepare feedingstuffs; (ii) Indicate the facilities used to store products for cleaning and disinfection; (iii) Indicate, 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; (iv) Indicate, where necessary, the name of the feed materials that the operator intends to prepare.
11.15.04	(Article 88 (2) (889/2008)) The measures taken by operators, to guarantee compliance with this Regulation must include: (i) In particular an indication of the precautionary measures to be taken in order to reduce the risk of contamination by unauthorised substances or products, the cleaning measures implemented and the monitoring of their effectiveness; (ii) Identification of all elements of their activities crucial for guaranteeing at all times that the products prepared in such units comply with the requirements of this Manual; (iii) The establishment and implementation of, compliance with and updating of appropriate procedures, based on the principles of the HACCP (Hazard Analysis and Critical Control Points) system.
11.15.05	(Article 88 (3) (889/2008)) OF&G shall use these procedures to carry out a general evaluation of the risks attendant on each preparation unit and to draw up an inspection plan. This inspection plan must provide for a minimum number of random samples depending on the potential risks.

Inspection Visits

11.15.06	(Article 90 (889/2008)) In addition to the complete annual visit: (i) OF&G must make targeted visits based on a general evaluation of the potential risks of non-compliance with this Manual; (ii) OF&G 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 as they should be; (iii) All the premises used by the operator for the conduct of his activities may be inspected as frequently as the attendant risks warrant.

Documentation

11.15.07	(Article 89 (889/2008)) For the purposes of inspection of the operations records shall include information on the origin, nature and quantities of feed materials, additives, sales and finished products.
11.15.08	*The detailed requirements for record keeping are specified in Section 14 of this Manual.*

Receipt of Products

11.15.09	(Article 66 (889/2008)) On receipt of ingredients for organic feeds, operators must check the closure of the packaging or container where it is required, check the organic labelling (where appropriate) and cross-check this with information on accompanying documentation. The results of these checks should be recorded.

Processing Units

11.15.10	(Article 26 (889/2008)) When preparing products, operators must ensure that: (i) Organically-produced feedingstuffs or feedingstuffs derived therefrom, in-conversion feedingstuffs or feedingstuffs derived therefrom, and conventional feedingstuffs are effectively physically separated; (ii) All equipment used in units preparing compounded feedingstuffs covered in this Manual is completely separated from equipment used for compounded feedingstuffs not covered in this Manual.

Transporting products to other preparation units or storage premises

11.15.11	(Article 32 (889/2008)) Operators must ensure that the following conditions are met: (i) During transport, organically-produced feed, in-conversion feed and non organic feed must be effectively physically separated; (ii) The vehicles and/or containers which have transported non-approved products may be used to transport approved products if: (a) Suitable cleaning measures, the effectiveness of which has been checked, have been carried out before commencing the transport of products covered in this Manual. Operators must record these operations; (b) Operators must ensure that all appropriate measures are implemented, depending on the risks evaluated in accordance with Sections 11.15.05 and 11.15.06, and where necessary, guarantee that products which do not conform to these Standards cannot be placed on the market with an indication referring to organic farming; (c) The operator shall keep documentary records of such transport operations available for the control body or control authority; (iii) The finished products referred to in this Manual are transported separately from other finished products physically or in time; (iv) During transport, the quantity of products at the start and each individual quantity delivered in the course of a delivery round must be recorded.

11.16 Specific Rules for the Making of Wine

Scope

11.16.01	(Article 29b (1) (203/2012)) This section lays down specific rules for the organic production of the products of the wine sector as referred to in Article 1(1)(l) of Council Regulation (EC) No 1234/2007.
11.16.02	(Article 29b (2) (203/2012)) Commission Regulations (EC) No 606/2009 and (EC) No 607/2009 shall apply, save as explicitly provided otherwise in this section.

Use of Certain Products and Substances

11.16.03	(Article 29c (1) (203/2012)) For the purposes of Section 11.1.05 (a), products of the wine sector shall be produced from organic raw material.
11.16.04	(Article 29c (2) (203/2012)) For the purposes of Section 11.1.05 (b), only products and substances listed in Section 10.3.05 can be used for the making of products of the wine sector, including during the processes and oenological practices, subject to the conditions and restrictions laid down in Regulation (EC) No 1234/2007 and Regulation (EC) No 606/2009 and in particular in Annex I A to that Regulation.
11.16.05	(Article 29c (3) (203/2012)) Products and substances listed in Section 10.3.05 of this Manual and marked with an asterisk, derived from organic raw material, shall be used if available.

Oenological Practices and Restrictions

11.16.06	(Article 29d (1) (203/2012)) Without prejudice to Sections 11.16.03 to 11.16.05 and to specific prohibitions and restrictions provided for in Sections 11.16.07 to 11.16.09 only oenological practices, processes and treatments, including the restrictions provided for in Article 120c and 120d of Regulation (EC) No 1234/2007 and in Articles 3, 5 to 9 and 11 to 14 of Regulation (EC) No 606/2009 and in their Annexes, used before 1 August 2010 are permitted.
11.16.07	(Article 29d (2) (203/2012)) The use of the following oenological practices, processes and treatments is prohibited: a) partial concentration through cooling according to point (c) of Section B.1 of Annex XVa to Regulation (EC) No 1234/2007; b) elimination of sulphur dioxide by physical processes according to point 8 of Annex I A to Regulation (EC) No 606/2009; c) electrodialysis treatment to ensure the tartaric stabilisation of the wine according to point 36 of Annex I A to Regulation (EC) No 606/2009; d) partial dealcoholisation of wine according to point 40 of Annex I A to Regulation (EC) No 606/2009; e) treatment with cation exchangers to ensure the tartaric stabilisation of the wine according to point 43 of Annex I A to Regulation (EC) No 606/2009.

11.16.08	(Article 29d (3) (203/2012)) The use of the following oenological practices, processes and treatments is permitted under the following conditions: a) for heat treatments according to point 2 of Annex I A to Regulation (EC) No 606/2009, the temperature shall not exceed 70 °C; b) for centrifuging and filtration with or without an inert filtering agent according to point 3 of Annex I A to Regulation (EC) No 606/2009, the size of the pores shall be not smaller than 0.2 micrometer.
11.16.09	(Article 29d (4) (203/2012)) The use of the following oenological practices, processes and treatments shall be re-examined by the Commission before 1st August 2015 with a view to phase out or to further restrict those practices: a) heat treatments as referred to in point 2 of Annex IA to Regulation (EC) No 606/2009; b) use of ion exchange resins as referred to in point 20 of Annex IA to Regulation 606/2009; c) reverse osmosis according to point (b) of section B.1 of Annex XVa to Regulation (EC) No 1234/2007.
11.16.10	(Article 29d (5) (203/2012)) Any amendment introduced after 1 August 2010, as regards the oenological practice, processes and treatments provided for in Regulation (EC) No 1234/2007 or Regulation (EC) No 606/2009, may be applicable in the organic production of wine only after the adoption of the measures necessary for the implementation of the production rules provided for in Section 11.1.05 (3) and, if required, an evaluation process according to Section 11.1.07.

Catastrophic Circumstances

11.16.11	(Article 47 (e) (889/2009)) Defra may authorise, on a temporary basis, the use of sulphur dioxide up to the maximum content to be fixed in accordance with the Annex 1 B to Regulation (EC) No 606/2009 if the exceptional climatic conditions of a given harvest year deteriorate the sanitary status of organic grapes in a specific geographical area because of severe bacterial attacks or fungal attacks, which oblige the winemaker to use more sulphur dioxide than in previous years to obtain a comparable final product. Upon approval by Defra, the individual operators shall keep documentary evidence of the use of the above exceptions.

Transitional Measures

11.16.12	(Article 96 (10) (889/2008)) Stocks of wines produced until 31 July 2012 in accordance with either Regulation (EEC) No 2092/91 or Regulation (EC) No 834/2007 may continue to be brought on the market until stocks are exhausted, and subject to the following requirements: a) the Community organic production logo as referred to in 4.2.08, called from 1 July 2010 the 'Organic logo of the EU' may be used provided that the wine-making process complies with Section 11.16 of this Manual;

11.16.12 cont.	b)	operators using the 'Organic logo of the EU' shall keep recorded evidence, for a period of at least five years after they placed on the market the wine obtained from organic grapes, including of the corresponding quantities of wine in litres, per wine category and per year;
	c)	where the evidence referred to in point (b) above is not available, such wine may be labelled as 'wine made from organic grapes', provided that it complies with the requirements of this Regulation except those provided for in Section 11.16 of this Manual;
	d)	wine labelled as 'wine made from organic grapes' cannot bear the 'Organic logo of the EU'.