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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007 -Outcome of the last trilogue

I. INTRODUCTION

The MT Presidency obtained a revised mandate at the SCA on 26 June. With this mandate, based on the document 10460/17 and the modifications introduced through room documents 1 and 2 delivered during that meeting (WK 7504 2017), a final round of negotiation with the European Parliament and the Commission was held on 28 June 2017.

The outcome of this trilogue was very positive as all parties show the necessary flexibility and willingness to finalise this dossier. After a one day round of negotiations, an agreement was finally reached on the organic file. The changes resulting from the Trilogue are marked in **red bold** in the revised text (**Annex I**).

It was confirmed by all parties that, although a political agreement was reached, this new text still needs to undergo legal and technical adaptations to ensure, in particular, the necessary legal quality and coherency throughout the text. Once this new text is available, SCA will consider it in a view of authorizing the SCA Chair to send the usual formal letter to the COMAGRI Chair.

II. OUTCOME OF THE MAIN ISSUES TACKLED DURING THE TRILOGUE.

- **Non-authorised substances (Article XX, Article 20a and 20b)**

The revised mandate was acceptable for all parties without any change of nature.

- **Greenhouse (demarcated beds)**

Regarding the difficult issue on demarcated beds, the revised mandate (room document n°2 circulated at the SCA) was agreed by all parties without any changes. In particular, it means that, by way of derogation to the general plant productions rules, growing crops in demarcated beds will be allowed, for 10 years, for the surfaces that have been certified as organic for this practice before 28 June 2017 in Finland, Sweden and Denmark. In the meantime, the Commission shall issue a report on the use of this practice to be accompanied, if appropriate, by a legislative proposal.

- **Seeds (Article 10a)**

The specific provisions for marketing heterogeneous material and organic varieties suitable for organic production appeared to be, as anticipated, the most difficult part of the negotiations during the Trilogue. But all parties showed some flexibility on this matter. As a result, some changes have been made to the Council compromise text. In particular, some clarifications were brought in the section on principles (article 5) as regard the definition of 'organic varieties suitable for organic production' - i.e. it **is** a variety within the meaning of Article 5.2 of Regulation 2100/94 (see article 3(6)(e)) - and the conditions under which such varieties can be produced (see Article 5 (dce)). In addition, in relation to the procedure aiming at marketing heterogeneous material, it was agreed that the notification (communicated by a supplier) should be examined within 3 months (and not one month) by the Competent authority. Moreover, some clarifications have been also brought into the text concerning the motivations for rejection of the dossier by the competent authority (incompleteness and non compliance with this Regulation). Regarding the temporary experiments for organic varieties, the European Parliament, while having a strong preference to enshrine directly conditions in the basic act, finally accepted that Commission would issue a statement on this matter (see Annex II).

- **Database (Article 19a)**

The Article 19a of document 10460/17 was agreed by all parties.

- **Article 35**

On this point, the room document n°1 circulated at the end of SCA was agreed with slight changes. In particular, the reference to point 4.1.2.1 (db) was deleted, as it was considered that the derogation on the use of non-organic juveniles for new species in the organic production system should not be linked to the 15-year end date, given that the introduction of new species could not be precluded in the future.

In addition, the reference to point 1.3.5a (bees) was deleted in paragraph 2 as queen bees are not in the scope of the database.

To be noted also that the European Parliament agreed to drop paragraph 4.

- **Conversion (Article 8)**

Article 8(4)(b) was agreed, as outlined in document 10460/17, with no changes.

In addition, Article 8(4)(c) was slightly changed. It was indeed agreed that the conditions for marketing food products of plant origin (Article 8(4)(c)) should be similar to the ones for feed products of plant origin (i.e. it contains only one agricultural crop ingredient and a conversion period of at least 12 months before the harvest has been complied with).

- **Labelling (Article 21)**

The text as outlined in document 10460/17 was agreed by all parties, with the exception of the last part under square brackets in Article 21(3), which was deleted.

- **Controls (Chapter Va)**

The Chapter on controls was agreed, as outlined in document 10460/17. The main changes relate to Article 26 on group of operators, to clarify that the turnover ceiling under Article 26(1)(b) refers to the turnover or standard output of the organic production only.

- **Animal welfare (Annex II, part II, point 1.7.9)**

The text, as outlined in document 10460/17, was agreed with the deletion from the derogation of the removal of antlers.

- **Poultry house (Article 3(43c), Article 11(4), Annex II, part II, points 1.8.4.4 (da)/(db))**

The definition of 'poultry house' was agreed by all parties. As a result, the implementing act foreseen under Article 11(4) was deleted. Points 1.8.4.4(da) and 1.8.4.4(db) under Annex II, Part II were agreed as set out in document 10460/17.

- **Non-opinion clause (Article 37)**

The text as set out in document 10460/17 was agreed. The Commission announced that it will issue a statement.

- **Aquaculture (Article 7(3)(iii))**

The Article 7(3)(iii), as set out in document 10460/17, was agreed.

- **Baby food (Annex II, part IV, point 2.2.2(e))**

The Point 2.2.2(e) was agreed as set out in document 10460/17.

- **Imports (Article 28)**

Article 28(1) was agreed as set out in document 10460/17.

- **Trade equivalence (Article 30)**

The text was agreed with the deletion of the text under square brackets. The European parliament announced its intention to issue a statement.

- **Recognition of control authorities and control bodies (Article 41)**

At the request of the Commission, to avoid any disruptions in trade, it was agreed to extend the expiry period for a maximum of 3 years concerning the recognition of control authorities and control bodies granted under Article 33(3) of Regulation (EC) No 834/2007.

- **Annexes Va and Vc**

These annexes were dropped. The Commission committed to tackle the development of the organic plant breeding sector in the Organic Action Plan.



Revised consolidated text based on the outcome of T18 on 28/06/2017Recitals (to be completed)

~~[According To Regulation (EC) No 1107/2009, the Union is divided into zones with comparable agricultural, plant health and environmental (including climatic) conditions. Denmark, Estonia, Latvia, Lithuania, Finland and Sweden are qualified in the same zone according to that Regulation. Since the agricultural, plant health and environmental (including climatic) conditions are making soil-related crop cultivation much more difficult during long periods during the year, derogations to the 'soil-related crop cultivation' should be allowed under certain conditions. The same should apply to third countries which present agricultural, plant health and environmental (including climatic) conditions comparable to those Member States.]~~

PM:+ recital on Art 11(4) and 12(4) to circumscribe the term "shall, as appropriate"

+ recital to indicate the steps the COM has to follow to launch the experiments on organic varieties suitable for organic production

Chapter I

Subject matter, scope and definitions

Article 1

Subject matter

This Regulation establishes the principles of organic production and lays down the rules concerning organic production, ~~processing, distribution, certification~~, the use of indications referring [...] to **organic production** in labelling and advertising **as well as rules on controls additional to those laid down in Regulation (EU) XXX on OCR.**

Article 2

Scope

1. This Regulation shall apply to [...] **the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the Treaty on the Functioning of the European Union ('the Treaty') or originating from these products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, or imported into or exported [...] from the Union:**

- (a) live or unprocessed agricultural products, including seed and other plant reproductive material;**
- (b) processed agricultural products for use as food;**
- (c) feed;**

and to other products **closely linked to agriculture listed in Annex I to this Regulation which are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported or exported.**

The products of hunting and fishing of wild animals shall not be considered as organic products.

2. This Regulation shall apply to any operator involved in activities, at any stage of production, preparation and distribution, relating to the products referred to in paragraph 1.

Mass catering operations carried out by a mass caterer as defined in point (d) of Article 2(2) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council shall not be subject to this Regulation.

Member States may apply national rules or, in the absence thereof, private standards on **the production**, labelling and control of products originating from mass-catering operations. **The organic production logo of the European Union shall not be used in the labelling, presentation and advertising of these products or to advertise the mass caterer.**

3. This Regulation shall apply without prejudice to related Union legislation, **in particular** in the fields of [...] safety of the food chain, animal health and welfare, plant health, and plant reproductive material [...].

4. This Regulation shall apply without prejudice to other specific Union provisions relating to the placing of products on the market and, in particular, to Regulation (EU) No 1308/2013 of the European Parliament and of the Council, and to Regulation (EU) No 1169/2011.

5. In order to take into account new information on production methods or material or international commitments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 [...] **amending by adding** to the list of products set out in Annex I. Only products which are closely linked to agricultural products shall be eligible for inclusion in that list.

Article 3

Definitions

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

(1) ‘organic production’ means the use of production methods compliant with this Regulation, at all stages of production, preparation and distribution, **and also during the conversion period referred to in Article 8;**

(1a) ‘organic products’ means products coming from or related to organic production, **excluding the products produced during the conversion period referred to in Article 8;**

[...]

(3) ‘agricultural raw material’ means an agricultural product that has not been subjected to any operation of preservation or processing;

~~†~~(4) ‘preventive measures’ means measures to be taken **by operators at all stages of production, preparation and distribution** in order to ensure **the preservation of biodiversity**, soil quality as well as prevention and control of pests and [...] **diseases (for plants and animals) [...] and to avoid negative effects on the environment and on animal and/or plant health;**~~†~~

~~†~~(4a) ‘precautionary measures’ means measures to be taken by operators at all stages of production, preparation, and distribution ~~in order to ensure compliance of organic production with this Regulation [as well as to prevent, in particular, avoid contamination with products or substances which that are not authorised to be used in organic production in accordance with this Regulation and under this Regulation, to avoid commingling of organic products with non-organic products. and to avoid effects on the environment and on human, animal or plant health which are not in accordance with this Regulation]~~~~†~~²;

(5) ‘conversion’ means the transition from non-organic to organic production within a given period of time **during which the provisions of this Regulation concerning organic production are applied;**

¹ ~~for A list T18~~

² ~~for A list T18~~

(5a) ‘in-conversion products’ means products that are produced during the conversion period in accordance with Article 8;

(6a) ‘holding’ means all the production units operated under a single management for the purpose of producing live or unprocessed agricultural products, ~~originating from agriculture,~~ including products originating from aquaculture and beekeeping, as referred to in Article 2(1)(a) and/or ~~to producing~~ products ~~of~~ listed in Annex I to this Regulation, except essential oils and yeast;

(6b) ‘production unit’ means all assets of a holding, such as primary production premises, land parcels, pasturages, open air areas, livestock buildings, hives, fish ponds, containment systems or sites for algae or aquaculture animals, rearing units, shore or seabed concessions, the premises for the storage of crops, crop products, algae products, animal products, raw materials and any other relevant inputs;

(6d) ‘organic production unit’ means a production unit which is managed in compliance with the requirements applicable to organic production, excluding during the conversion period referred to in Article 8;

(6e) ‘in-conversion production unit’ means a production unit which is managed in compliance with the requirements of organic production during the conversion period referred to in Article 8;

(6f) ‘non-organic production unit’ means a production unit, which is not managed in compliance with the requirements of organic production;

(6) ‘operator’ means the natural or legal person responsible for ensuring that this Regulation is complied with at all stages of production, preparation and distribution under their control;

[...]

(8) ‘farmer’ means a natural or legal person, or a group of natural or legal persons, regardless of the legal status granted to such group and its members by national law,-who exercises an agricultural activity;

(9) 'agricultural area' means agricultural area as defined in point (e) of Article 4(1) of Regulation (EU) No 1307/2013;

(10) 'plants' means plants as defined in point 5 of Article 3 of Regulation (EC) No 1107/2009;

~~†(10a) 'organic plant breeding and variety development' means the enhancement of genetic diversity coupled with reliance on natural reproductive ability; Organic plant breeding is aimed at the the development of new varieties which are particularly suited for organic production systems and undertaken in line with the requirements of this Regulation. It involves a holistic approach that respects natural crossing barriers and is based on fertile plants that can establish a viable relationship with the living soil. Organic plant breeding is undertaken under these organic plant breeding conditions in line with the requirements of this Regulation.†~~

~~†(6c) plant reproductive material" means plants as well as all forms parts of plants at any growth stage including seeds, capable of, and intended for, producing entire plants;†~~

~~†(6d) 'organic heterogeneous material' means plant grouping within a single botanical taxon of the lowest known rank, which:~~

~~(i) presents common phenotypic characteristics;~~

~~(ii) is, however, characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that this plant grouping is represented by the material as a whole, and not by a small number of units;~~

~~(iii) does not meet the definition of variety within the meaning of Article 5(2) of Regulation 2100/94;~~

~~(iv) is not a mixture of varieties;~~

~~(v) has been produced in accordance with the requirements of this Regulation.†~~

~~†(6e) An 'organic variety suitable for organic production' is a plant grouping within a single botanical taxon of the lowest known rank, which fulfils the following requirements:~~

~~(i) is characterised by a high level of genetic and phenotypical diversity between individual reproductive units;~~

~~†(ii) it results from organic ~~plant~~ breeding activities as referred to in Annex II, Part I, point 1.4.1b;~~

~~†(iii) it is coupled with reliance on natural reproductive ability and is contained within natural crossing barriers.~~

~~†(iv) is/may be a variety within the meaning of Article 5.2 of Regulation 2100/94 (Community Plant variety rights);~~

~~†(10e) 'mother plant' means an identified plant from which plant reproductive material is taken for reproduction of new plants.~~

†(10d) 'generation' means a group of plants constituting a single step in the line of descent of plants;

~~(10e) 'organic animal breeding' means the enhancement of genetic diversity coupled with reliance on the natural reproductive ability of the animals concerned. Organic animal breeding shall secure optimum compliance with the requirements of this Regulation, focussing on disease resistance, longevity, breeding value, and adaptation to climatic and natural conditions, and shall promote breeding aimed at slow growth where relevant;~~

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

(12) 'plant products' means plant products as defined in point 6 of Article 3 of Regulation (EC) No 1107/2009;

(13) ‘pest’ means a pest as defined in Article 1(1) of Regulation (EU) No XX/XXXX (protective measures against pests of plants);

(13b) ‘biodynamic preparations’ means mixtures traditionally used in biodynamic farming ~~[and numbered from 500 to 508 [as defined by Demeter]];~~

(14) ‘plant protection products’ means the products referred to in Article 2 of Regulation (EC) No 1107/2009;

(15) ‘livestock production’ means the production of domestic or domesticated terrestrial animals, including insects;

(16) ‘veranda’ means an additional, roofed, uninsulated, outdoor part of a ~~livestock~~-building ***intended for poultry***, the longest side being usually equipped with wire fencing or netting with outdoor climate, natural **and/or** artificial illumination and a littered floor;

(16a) ‘pullets’ means young animals of the Gallus gallus species of an age of less than 18 weeks;

(16b) ‘laying hens’ means animals of the Gallus gallus species intended for the production of eggs for consumption and of an age of at least 18 weeks;

~~**(16c) ‘broilers’ means animals of the Gallus gallus species kept for meat production;**~~

(16d) ‘usable area’ means an area as defined in Council Directive 1999/74/EC;

(17) ‘aquaculture’ means aquaculture as defined in point (25) of Article 4(1) of Regulation (EU) No 1380/2013 of the European Parliament and of the Council³;

~~**{(17a) ‘aquaculture products’: means aquaculture products as defined in point 34 of Article 4 (1) of Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy⁴;**}~~

³ Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

⁴ OJ L 354, 28.12.2013, p. 22.

(17a) ‘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 stabilise the environment for the aquaculture animals;

(17b) ‘energy from renewable sources’ means renewable non-fossil energy sources such as wind, solar, geothermal wave, tidal, hydropower, landfill gas, sewage treatment plant gas and biogases;

(17c) ‘hatchery’ in the framework of aquaculture and algae production means a place of breeding, hatching and rearing through the early life stages of aquaculture animals, finfish and shellfish in particular;

(17d) ‘nursery’ in the framework of aquaculture and algae production means a place where an intermediate production system is applied between the hatchery and grow-out stages. The nursery stage is completed within the first third of the production cycle with the exception of species undergoing a smoltification process;

(17e) ‘pollution’ in the framework of aquaculture and algae production means the direct or indirect introduction into the aquatic environment of substances or energy as defined in Directive 2000/60/EC of the European Parliament and of the Council⁵ and in Directive 2008/56/EC of the European Parliament and of the Council⁶, in the waters to which those Directives apply, respectively;

(17f) ‘polyculture’ in the framework of aquaculture and algae production means the rearing of two or more species usually from different trophic levels in the same culture unit;

(17g) ‘production cycle’ in the framework of aquaculture and algae production means the lifespan of an aquaculture animal or algae from the earliest life stage (fertilised eggs in the case of aquaculture animals) to harvesting;

⁵ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

⁶ Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for Community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19).

(17h) ‘locally grown species’ in the framework of aquaculture and algae production means species which are neither alien nor locally absent species under Council Regulation (EC) No 708/2007, as well as the species listed in Annex IV to that Regulation;

(17i) ‘stocking density’ in the framework of aquaculture and algae production means the live weight of aquaculture 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;

(18) ‘veterinary treatment’ means all courses of a curative or preventive treatment against one occurrence of a specific disease;

{(19) ‘veterinary medicinal products’ means veterinary medicinal products as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council⁸;}

{(20) ‘preparation’ means the operations of preserving or processing of organic **or in-conversion** products, **or any other operation that is carried out on an unprocessed product without altering the initial product**, such as [...] slaughtering, [...] cutting [...], **cleaning or milling** [...], **and/or** packaging, labelling or alterations made to the labelling relating to organic production;}

(21) ‘food’ means food as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁷

(22) ‘feed’ means feed as defined in point 4 of Article 3 of Regulation (EC) No 178/2002;

(23) ‘feed material’ means feed material as defined in point (g) of Article 3(2) of Regulation (EC) No 767/2009 of the European Parliament and of the Council⁹;

⁷ Council Regulation (EC) No 708/2007 of 11 June 2007 concerning use of alien and locally absent species in aquaculture (OJ L 168, 28.6.2007, p. 1).

⁸ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p.1).

⁹ Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1).

[...]

(25) ‘placing on the market’ means placing on the market as defined in point 8 of Article 3 of Regulation (EC) No 178/2002;

(26) ‘traceability’ means traceability as defined in point 15 of Article 3 of Regulation (EC) No 178/2002;

(27) ‘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;

[...]

(29) ‘ingredient’ means an ingredient as defined in point (f) of Article 2(2) of Regulation (EU) No 1169/2011 **or for products other than food, any substance or product used in the manufacture or preparation of products, that is still present in the finished product, even in altered form.**

{(30) ‘labelling’ means **any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a product and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such product;** labelling as defined in point (j) of Article 2(2) of Regulation (EU) No 1169/2011;}

-(31) ‘advertising’ means any presentation of [...] products 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;}

(32) ‘competent authorities’ means competent authorities as defined in point 5 ~~3~~ of Article 2 ~~3~~ of Regulation (EU) No XXX/XXXX [Official controls Regulation];

(33) ‘control authority’ means **an organic** control authority for organic production and labelling of organic products as defined in point 4 39 of Article 3 2 of Regulation (EU) No XXX/XXXX [Official controls Regulation] **as well as an authority recognised by the Commission or by a third country recognised by the Commission to carry out controls in third countries for the import of organic products into the Union;**

(34) ‘control body’ means a delegated body as defined in point 5 38 of Article 3 2 of Regulation (EU) No XXX/XXXX [Official controls Regulation], as well as a body recognised by the Commission or by a third country recognised by the Commission to carry out controls in third countries for the import of organic products into the Union;

(35) ‘non-compliance’ means non-compliance with this Regulation, **with the delegated and implementing acts adopted in accordance with this Regulation;**

(35a) ‘compliance’ means compliance with this Regulation and its Annexes, with the delegated and implementing acts adopted in accordance with this Regulation and with other Regulations to which this Regulation refers;

~~{(36) ‘genetically modified organism’ means a genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council¹⁰ which is not obtained through the techniques of genetic modifications listed in Annex I.B to that Directive, hereinafter referred to as ‘GMO’;}~~

(37) ‘produced from GMOs’ means derived in whole or in part from GMOs but not containing or consisting of GMOs;

(38) ‘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;

(39) ‘food additive’ means a food additive as defined in point (a) of Article 3(2) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council¹¹ ;

¹⁰ 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 (OJ L 106, 17.4.2001, p. 1).

¹¹ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

(40) ‘feed additive’ means a feed additive as defined in point (a) of Article 2(2) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council¹²;

(40a) 'engineered nanomaterial' means engineered nanomaterial as defined in point (t) of Article 2(2) of Regulation (EU) No1169/2011;

(41) ‘equivalence’ means meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity;

(41a)‘processing aid’ means processing aid as defined in point (b) of Article 3(2) of Regulation (EC) No 1333/2008;

(42) ‘food enzyme’ means a food enzyme as defined in point (a) of Article 3(2) of Regulation (EC) No 1332/2008 of the European Parliament and of the Council¹³;

(43) ‘ionising radiation’ means ionising radiation as defined in Article 1 of Council Directive 96/29/Euratom¹⁴.

(43a) ‘pre-packed food’ means a pre-packed food as defined in Article 2(2)(e) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council;

~~{(43c) —‘poultry house’ means a covered, independent structure fitted out in such a way as to protect the animals housed within it from bad weather;}~~

{(43c) ‘poultry house’ means a building for accommodating flocks of poultry, which includes all surfaces covered by roofs (fixed or mobile), including a veranda. The house may be subdivided into separate compartments, each accommodatunge a single separate-flocks. }

¹² Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

¹³ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7)

¹⁴ 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 ionizing radiation (OJ L 159, 29.6.1996, p. 1).

(43e) 'soil-related crop cultivation' means production in living soil or in soil mixed or fertilised with materials and products allowed in organic production in connection with the subsoil and bedrock;

~~{(43i) 'unprocessed products': means unprocessed products as defined in point (n) of Article 2 (1) of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs¹⁵, irrespective of packaging or labelling operations;}~~

~~{43(j)'processed products': means processed products as defined in point (o) of Article 2 (1) of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, irrespective of packaging or labelling operations.}~~

~~{43(k) 'processing' means any action as defined in point (m) of Article 2 (1) of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs¹⁶, including the use of substances referred to in Article 19 of this Regulation. Packaging or labelling operations shall not be considered as processing;}~~

~~43(l) 'integrity of organic or in-conversion products', in relation to an organic or in-conversion product means that the product does not present non-compliances with the requirements of this Regulation that: the absence of any failure by that product to comply with this Regulation which:~~

- ~~– affects the organic or respectively in-conversion characteristics of the product throughout in any all stages of its production, preparation and distribution and export; and/or~~
- ~~– is are repetitive or intentional.~~

~~43(m) a pen shall means an enclosure that must includes a part where animals are provided with protection from the weather;~~

¹⁵ OJ L 139, 30.4.2004, p. 1.

¹⁶ OJ L 139, 30.4.2004, p. 1.

Chapter II

[...]Objectives of, and principles for, organic production

Article 3a

Objectives

~~This Regulation shall provide the basis for the sustainable development of organic production and its positive effects on the environment, while ensuring the effective functioning of the internal market and fair competition, thereby helping farmers to achieve a fair income, ensuring consumer confidence and protecting consumer interests~~

The organic production shall pursue the following general objectives:

- contribution to protection of the environment *and* the climate;
- maintenance of the long-term fertility of soils;
- contribution to a high level of biodiversity;
- substantial contribution to a non-toxic environment;
- contribution to high animal welfare standards and, in particular, meet animals' species-specific behavioural needs;
- encouragement of short distribution channels and local production in the various areas of the Union;
- encouragement of the preservation of rare and/or native breeds in danger of extinction.

- contribution to the development of the offer of plant genetic material adapted to the specific needs and objectives of organic agriculture;
- contribution to a high level of biodiversity, notably by using diverse plant genetic material, such as heterogeneous material and organic varieties ~~and seeds and propagating material~~ suitable for organic production;
- ~~[produce, wherever possible, organic varieties by relying on natural reproductive ability and contained within natural crossing barriers;]~~
- foster the development of organic plant breeding activities in order ~~to contribute¹⁷~~ to favourable economic perspectives of the organic production sector.

Article 4

General principles

Organic production is a sustainable management system [...] that is based on the following general principles:

(a) respect for nature's systems and cycles and sustainment and enhancement of the state of soil, water **and** air, [...] of the health of plants and animals and of the balance between them;

(aa) preservation of natural landscape elements such as ‘natural heritage sites’;

[...]

(c) responsible use of energy and natural resources, such as water, soil, organic matter and air;

¹⁷ — for A list T18

(gb) production of a wide variety of high quality food and other agricultural and aquacultural products that respond to consumers' demand for goods produced by the use of processes that do not harm the environment, human health, plant health or animal health and welfare;

(gc) ensuring the integrity of organic production at all stages of production, processing and distribution of food and feed;

[...]

~~**{(de) encouragement of short distribution channels and local production in the various areas of the Union;}**~~

(e) appropriate design and management of biological processes based on ecological systems using natural resources which are internal to the system by methods that:

(i) use living organisms and mechanical production methods;

(ii) practice [...] **soil-related** crop cultivation and **land-related** livestock production or practice aquaculture which complies with the principle of sustainable exploitation of **aquatic resources** [...];

(iii) exclude the use of GMOs and products produced from or by GMOs with the exception of veterinary medicinal products;

are based **on risk assessment, and** the use of **precautionary measures and** preventive measures, when appropriate;

(f) restriction of the use of external inputs. Where external inputs are required or the appropriate management practices and methods referred to in point (e) do not exist, these shall be limited to:

(i) inputs from organic production, **in the case of plant reproductive material, priority shall be given to varieties selected for their ability to meet the specific needs and objectives of organic farming;**

- (ii) natural or naturally-derived substances;
- (iii) low solubility mineral fertilisers;
- (g) adaptation, where necessary, and within the framework of this Regulation, of the production process, taking account of the sanitary status, regional differences in ecological balance, climate and local conditions, stages of development and specific husbandry practices;
- (ga) exclusion of animal cloning, rearing artificially induced polyploid animals and ionising radiation from the whole organic food chain;**
- (gb) observance of a high level of animal welfare respecting species-specific needs;**

Article 5

Specific principles applicable to agricultural activities and aquaculture

In the framework of agricultural activities and aquaculture, organic production shall in particular be based on the following specific principles:

- (a) maintenance and enhancement of soil life and natural soil fertility, soil stability, soil water retention and soil biodiversity preventing and combating loss of soil organic matter, soil compaction and soil erosion, and the nourishing of plants primarily through the soil ecosystem;
- (b) limitation of the use of non-renewable resources and external inputs to a minimum;
- (c) recycling of wastes and by-products of plant and animal origin as input in plant and livestock production;

(d) maintenance of plant health by preventive measures, in particular the choice of appropriate species, varieties or [heterogeneous material /~~populations~~] resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and protection of the natural enemies of pests;

(da) use of seeds and animals with a high degree of genetic diversity, resistance against diseases and longevity;

~~[(db) choice of plant breeds varieties having regard to the particularities of the organic production systems, focussing on agronomic performance, disease resistance, adaptation to diverse local soil and climate conditions and respect of the natural crossing barriers];~~

~~[(dc) equal access [of for] farmers to heterogeneous material, [open pollinated varieties/seeds from open pollination] [organic varieties] and hybrid varieties and the use of traditional crop varieties obtained from their own farm in order to foster genetic resources adapted to the special conditions of organic production] use of organic plant reproductive material such as organic heterogeneous material, and organic varieties suitable for organic production];~~

~~(dce) production of organic varieties through natural reproductive ability and focussing on containment within natural crossing barriers;~~

~~[(dd) where possible, use by farmers of traditional crop varieties including those obtained from their own farm in order to foster genetic resources adapted to the special conditions of organic production.]~~

~~[(dd) without prejudice to Article 14 of Regulation 2100/94, , and to the national plant variety rights granted by the law of the Member States, possibility for farmers to use plant reproductive material obtained from their own farm in order to foster genetic resources adapted to the special conditions of organic production];~~

(e) choice of ~~{animal}~~ breeds having regard to a high degree of genetic diversity, the capacity of animals to adapt to local conditions, ~~{and/or with a high degree of genetic diversity}~~, ~~{their breeding value}~~, their longevity, their vitality ~~{and longevity}~~ and their resistance to disease or health problems; the practice of site-adapted and land-related livestock production; the application of animal husbandry practices, which enhance the immune system and strengthen the natural defence against diseases, in particular including regular exercise and access to open air areas and pastureland;

[...]

(g) feeding of livestock with organic feed composed of agricultural ingredients from organic production and of natural non-agricultural substances;

(jb) production of organic livestock products derived from animals that have been raised on organic holdings since their birth or hatching and throughout their life;

[...]

(i) continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems;

(j) feeding of aquatic organisms with feed from sustainable exploitation of fisheries in accordance with Regulation (EU) No 1380/2013 or with organic feed composed of agricultural ingredients from organic production, including organic aquaculture, and of natural non-agricultural substances.

(k) avoiding any endangerment of species of conservation interest that might arise from organic production.

Article 6

Specific principles applicable to the processing of organic food [...]

Production of processed organic food [...] shall, in particular, be based on the following specific principles:

- (a) production of organic food from organic agricultural ingredients; ~~{except where an ingredient is not available as an organic product at a certain point in time. In such cases, non-organic ingredients may, exceptionally, be authorised by the competent authority of the Member State concerned. Such authorisation shall be notified to the Commission and published by the Commission in such a way as to make this information accessible}~~

[...]

- (b) [...] **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 cases of essential technological need or for particular nutritional purposes;

[...]

- (c) exclusion of substances and processing methods that might be misleading as regards the true nature of the product;

- (d) processing of food [...] with care, preferably through the use of biological, mechanical and physical methods.

- (ha) exclusion of food containing or consisting of ~~{artificially¹⁸}~~ engineered nanomaterials;

¹⁸ — A list at T18

Article 6a

Specific principles applicable to the processing of organic feed

Production of processed organic feed shall, in particular, be based on the following specific principles:

- (a) production of organic feed from organic feed materials;**
- (b) restriction of the use of feed additives and processing aids to a minimum extent and only in cases of essential technological or zootechnical needs or for particular nutritional purposes;**
- (c) exclusion of substances and processing methods that might be misleading as regards the true nature of the product;**
- (d) processing of feed with care, preferably through the use of biological, mechanical and physical methods.**

Chapter III

Production rules

Article 7

General production rules

1. Operators shall comply with the following general production rules:

(a) the entire [...] holding [...] shall be managed in compliance with the requirements of this Regulation applicable to organic production;

~~(b) [...] for the purposes mentioned in Article 19 and Article 19aa *and the uses mentioned in Annex II* in point 2.2 of Part IV and point 1.3 of Part VI of Annex II;~~ only products and substances authorised pursuant to [...] **these provisions** may be used in organic [...] production, ~~provided that the product or substance in question has been authorised for use in [...] organic production in accordance with Article 19 and Annex II with the relevant provisions of Union law [...] in accordance with national provisions based on Union law; and provided that their use has *also* been authorised for conventional production in accordance with the relevant provisions of Union law and [...] in accordance with national provisions based on Union law.~~

The following products and substances referred to in Article 2 (3) of Regulation (EC) No 1107/2009 shall be allowed for use in organic agriculture provided that they are authorised pursuant to Regulation (EC) No 1107/2009:

- **safeners, synergists and co-formulants as components of plant protection products;**
- **adjuvants to be mixed with plant protection products;**

The use of products and substances used for other purposes [...] not regulated in this Regulation are allowed to be used in organic production provided that their use respects the principles laid down in Chapter II;

(c) the use of ionising radiation for the treatment of organic food or feed, or of raw materials used in organic food or feed shall be prohibited;

(ca) the use of animal cloning and the rearing of artificially induced polyploid animals is prohibited;

(cb) preventive and precautionary measures shall be taken, as appropriate, at all stages of production, preparation and distribution;

[...]

3. Notwithstanding paragraph 1 (a), a holding may be split into clearly and effectively separated organic, in-conversion and non-organic production units, provided that for the non-organic production units:

(i) as regards livestock, different species are involved;

(ii) as regards plants, different varieties that can be easily differentiated are involved;

~~[(iii) as regards algae and aquacultural animals, different species are involved;]~~

As regards algae and aquaculture animals, the same species may be involved, provided that there is a clear and effective separation between the productions sites or units.

~~As regards aquaculture, the same species may be involved, provided that there is a clear and effective separation between the productions sites.]~~

By way of derogation to point (ii), in the case of perennial crops which require a cultivation period of at least three years, different varieties that cannot be easily differentiated or the same varieties may be involved provided that the production in question forms part of a conversion plan and that the conversion to organic production of the last part of the area related to the production in question begins within the shortest possible period and is completed within a maximum of five years.

In such cases:

(a) the competent authority ~~for where appropriate, control authority or control body,~~¹⁹ shall be notified of the harvest of each of the products concerned at least 48 hours in advance;

(b) upon completion of the harvest, the producer shall inform the competent authority ~~for where appropriate, control authority or control body,~~²⁰ of the exact quantities harvested on the units concerned and of the measures applied to separate the products;

(c) the conversion plan and the measures to ensure the effective and clear separation shall be confirmed each year by the competent authority ~~for where appropriate, control authority or control body,~~²¹ after the start of the conversion plan.

By way of derogation to points (i) and (ii) and (iii), in the case of research and educational centres, nurseries, seed multipliers, hatcheries in the framework of aquaculture and algae production and breeding operations, the requirements concerning different species and varieties shall not apply.

4. Where, in the cases referred to in paragraph 3, not all production units of a holding are managed under organic production rules, the farmers and operators shall keep the products used for the organic and in-conversion production units separate from those used for the non-organic production units. Farmers and operators shall keep separate the products produced by the organic, in-conversion and non-organic production units.

Farmers and operators shall keep adequate records to show the effective separation of the production units and of the products.

¹⁹ — A list for T18

²⁰ — A list for T18

²¹ — A list for T18

6. In order to ensure quality, traceability and compliance with this Regulation as regards organic production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending by adding to the rules laid down in paragraph 3 in particular as regards products listed in Annex I to this Regulation.

Article 8

Conversion

1. Farmers and operators producing [...] **algae** or aquaculture animals shall respect a conversion period. During the whole conversion period they shall apply [...] **all** rules on organic production laid down in this Regulation and, in particular, the relevant rules on conversion set out in this Article and in Annex II.

2. The conversion period shall start at the earliest when the farmer or the operator producing [...] **algae** or aquaculture animals has notified his activity to the competent authorities [...] **as referred to in article 24(1) and his holding is submitted to the organic certification and control system.**

[...]

3. No previous period may be recognised retroactively as being part of the conversion period **except where:**

(a) the land parcels were subject of measures defined in a programme implemented pursuant to Regulation (EU) No 1305/2013 provided that these measures ensure that products or substances not authorised for organic production have not been used on those land parcels; or

(b) proof can be provided by the operator that the land parcels were natural or agricultural areas which were not treated with products or substances not authorised for organic production for a period of at least three years.

4. Products produced during the conversion period shall not be marketed as organic or as in-conversion products.

However, the following products produced during the conversion period and in compliance with paragraph 1 may be marketed as in-conversion products:

(a) plant reproductive material;

~~(b) feed products of plant origin produced during the conversion period and in compliance with paragraph 1 may be marketed as in-conversion products provided that [the product contains only one agricultural crop ingredient and]~~ a conversion period of at least 12 months before the harvest has been complied with;

~~(c) food products of plant origin provided that the product contains only one agricultural crop ingredient and~~ a conversion period of at least 12 months before the harvest has been complied with.

[...]

6. In order to ensure quality, traceability and compliance with this Regulation as regards organic production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 [...] **amending by adding to** the rules set out in point 1.2.2 of Annex II, part II as regards conversion for species other than those regulated in Part II of Annex II.

The Commission shall, where appropriate, adopt implementing acts specifying the documents to be supplied in view of the recognition of previous retroactive period, as referred to in Article 8.3 (a) and (b).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 9

Prohibition of the use of GMOs

1. GMOs and products produced from or by GMOs shall not be used in food or feed or as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, plant reproductive material, micro-organisms and animals in organic production.
2. For the purposes of **the prohibition laid down in** paragraph 1, with regard to GMOs or products produced from ~~or by~~ GMOs for food and feed, operators may rely on the labels of a product or any other accompanying document, affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) No 1829/2003 of the European Parliament and of the Council²² or Regulation (EC) No 1830/2003 of the European Parliament and of the Council²³.
3. Operators may assume that no GMOs or products produced from ~~or by~~ GMOs have been used in the manufacture of purchased food and feed when such products are not labelled, or accompanied by a document, pursuant to the Regulations referred to in paragraph 2, unless they have obtained other information indicating that the labelling of the products concerned is not in conformity with those Regulations.
4. **For the purpose of the prohibition laid down in paragraph 1 with regard to products not covered by the provisions of paragraphs 2 and 3, operators using 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.**

²² Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

²³ Regulation (EC) 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

Plant production rules

1. Operators producing plants or plant products shall in particular comply with the detailed rules set out in Part I of Annex II. ~~and with the implementing acts referred to in paragraph 6.~~

~~2.~~ Each Member State shall ensure that a computerised database is established for listing the plant reproductive material obtained by the organic production method [...] available on its territory

3. In order to ensure quality, traceability and compliance with this Regulation as regards organic plant production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending [...] the [...] **detailed** plant production rules set out in Part I of Annex II as regards:

[...]

~~†~~ **derogations 1.1.a and 1.1.b**

- **use of plant reproductive material / use of seed or vegetative material not obtained from organic production as referred to in points 1.4.2 and 1.4.2.1.**

4. **In order to ensure quality, traceability and compliance with this Regulation as regards organic plant production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending by adding to the detailed plant production rules set out in Part I of Annex II as regards:**

- **the provisions concerning agreements with other agricultural holdings as referred to in point 1.5.5.**

- **the measures related to pest and weed management as referred to in point 1.6.1**

- detailed rules and cultivation practices for specific plants and ~~{plant products in²⁴}~~, including rules for sprouted seeds.

~~5. — The Commission shall adopt delegated acts amending by adding to *[point 1.1.d of Annex II, Part I]* specific conditions on the cultivation practices referred ~~[to therein]~~ with regard to rules on conversion, preventive measures including crop rotation, soil and crop health, ~~[use of energy and natural resources]~~, ~~[and]~~ nutrient and soil fertility management ~~/, and the [specific climatic conditions justifying the recourse to demarcated beds.]~~ ~~[limited to what is necessary in order to ensure conditions equal to production not subject to the derogation in point 1.1.d of Annex II, Part I.]~~~~

~~6. — The Commission shall adopt implementing acts laying down [...] rules on:~~

~~— [the application of point 1.4.2 of Annex II Part I, including the list of varieties or species for which point 1.4.2 cannot apply]~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).~~

~~Article 10a~~

~~Specific provisions for the marketing of organic heterogeneous material~~

~~1. Seed and other propagating material of organic heterogeneous material may be marketed without complying with the requirements for registration and the certification categories of pre-basic, basic and certified material, or the requirements for other categories, as set out in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, ~~2002/53/EC~~, ~~2002/54/EC~~, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC, or acts adopted pursuant to those Directives.~~

²⁴ — A list T18

2. Organic heterogeneous material may be marketed following a ~~notification~~ by the supplier to the responsible official bodies referred to in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC of a dossier containing:

(i) the contact details of the applicant;

(ii) the species and denomination of the heterogeneous material;

(iii) the description of the main agronomic and phenotypic characteristics that are common to that plant grouping, including ~~relevant~~ breeding methods, results from tests ~~, if available~~, the country of production and the parental material used;

(iv) a declaration of the applicant concerning the trueness of the foregoing elements;

(v) and a representative sample;

That ~~notification~~ shall be sent by registered letter with confirmation of receipt.

Within ~~one/ three~~ months after the date shown on the return receipt, and provided that no additional information was requested or no formal refusal ~~for reasons of incompleteness of the dossier or non-compliance with this Regulation~~ was communicated to the supplier, the competent authority shall be deemed to have acknowledged the notification and its content.

After express or implied acknowledgment of the ~~notification~~, the competent authority may proceed to the listing free of charge of the notified material.

The listing of an 'organic heterogeneous material' shall be communicated to other Member States and the Commission.

The material shall comply with provisions adopted in accordance with paragraph 3.

3. The Commission shall be empowered to adopt delegated acts (ie experts of the seeds directives), in accordance with Article 36, setting out rules concerning the production and marketing of organic heterogeneous material of particular genera or species, as regards:

(a) the description of the material, including the relevant breeding and production methods and parental material used;

(b) the minimum quality requirements of seeds lots, including (identity, specific purity, germination rates and sanitary quality);

(c) labelling, packaging ~~and marketing conditions~~;

(d) information and samples of production to be kept by the professional operators;

(e) where applicable, maintenance of the material.]

Article 11

Livestock production rules

1. Livestock operators shall in particular comply with the [...] **detailed** production rules set out in Part II of Annex II **and in the implementing acts referred to in paragraph 4.**

2. In order to ensure quality, traceability and compliance with this Regulation as regards organic livestock production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending [...] the detailed livestock production rules set out in Part II of Annex II as regards:

[...]

- the reduction of percentages ~~and the phasing out of the derogations²⁵~~ as regards the origin of animals as laid down in points ~~1.3.5a-1, 1.3.5.2., and 1.3.5.3., 1.3.5.4. and 1.3.5.4a²⁶~~ once the sufficient availability on the EU market of organic animals has been established;
- the limit of organic nitrogen linked to the total stocking density as referred to in point 1.6.6;

[...]

- feeding of bee colonies as referred to in point 1.8.6.2b ;

²⁵ — A list T18

²⁶ — A list T18

[...]

- acceptable treatments for disinfection of apiaries and for the fight against Varroa destructor as referred to in points ~~ex 2.5.4~~ 1.8.6.3 (b) and (e);

3. In order to ensure quality, traceability and compliance with this Regulation as regards organic livestock production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending by adding to the detailed livestock production rules set out in Part II of Annex II as regards:

- derogations as regards the origin of animals for species other than those regulated in Annex II, part II;
- nutrition for species other than those regulated in Part II of Annex II;
- housing conditions and husbandry practices for species other than those regulated in Part II of Annex II;
- health care for species other than those regulated in Part II of Annex II;
- animal welfare for species other than those regulated in Part II of Annex II;

4. The Commission shall, **as appropriate**, adopt implementing acts laying down rules on:

- the minimum period referred to in point 1.4.1. (g) to be respected for feeding of suckling animals with maternal milk;
- the stocking density and minimum surface for indoor and outdoor areas to be respected for specific livestock species to ensure, in accordance with points 1.6.3 and 1.7.2, that the developmental, physiological and ethological needs of animals are met, ~~including relevant definitions regarding such areas in respect of poultry~~;
- the characteristics and technical requirements of the minimum surface for indoor and outdoor areas;

- **the characteristics and technical requirements of buildings and pens for all livestock species, except for bees, to ensure, in accordance with point 1.7.2., that the developmental, physiological and ethological needs of animals are met;**
- **vegetation requirements and characterises of protected facilities and open air areas;**

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 12

Production rules for [...] algae and aquaculture animals

1. Operators producing [...] **algae** and aquaculture animals shall in particular comply with the [...] **detailed** production rules set out in Part III of Annex II **and in the implementing acts referred to in paragraph 4.**
2. In order to ensure quality, traceability and compliance with this Regulation as regards organic [...] **algae and aquaculture animals** production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending [...] the [...] production rules **for algae and aquaculture animals** as regards:

[...]
 - (a) **feed for carnivorous animals as referred to in Annex II, Part III, point 4.1.3.3;**
 - (b) **veterinary treatments for aquaculture animals as referred to in Annex II, Part III, point 4.1.4.2.**
3. In order to ensure quality, traceability and compliance with this Regulation as regards organic algae and aquaculture animals production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending [...] **by adding to** the [...] production rules **for algae and** aquaculture animals as regards:

[...]

(a) detailed conditions per species for broodstock management, breeding and juvenile production ~~{as referred to in point 4.1.2.2}~~;

(b) feed for certain aquaculture animals as referred to in Annex II, Part III, point 4.1.3.4.

4. The Commission shall, **as appropriate**, adopt implementing acts laying down detailed rules per species or group of species on the stocking density and on the specific characteristics for production and/or containment systems to ensure the species specific needs.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 13

Production rules for processed food [...]

1. Operators producing processed food [...] shall in particular comply with the [...] **detailed** production rules set out in Part IV of Annex II.

2. In order to ensure quality, traceability and compliance with this Regulation as regards organic processed food [...] production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 ~~{amending²⁷/amending by adding²⁸}~~ [...] the [...] **detailed** production rules for processed food [...] as regards:

[...]

(b) ~~{**precautionary and**²⁸}~~ preventive measures to be taken **as referred to in point 1.4 of Part IV of Annex II**;

²⁷ — A list T18

²⁸ — A list T18

(c) the **type**, composition and conditions of use [...] of products and substances allowed for use in processed food [...], **as laid down in point 2.2.2 of Part IV of Annex II;**

[...]

(h) the calculation of the percentage of agricultural ingredients referred to in Article 21(3)(a)(ii) and (b), **as laid down in point 2.2.3 of Part IV of Annex II, including the list of food additives authorised for use in organic production pursuant to Article 19 that shall are be calculated as agricultural ingredients;**

(i) [~~techniques used in food or feed processing.~~]

Such detailed production rules shall not include the possibility to use flavouring substances or flavouring preparations which are neither natural, according to Article 15(1)(e) and Article 16(2), (3) and (4) of Regulation 1334/2008 nor organic.²⁹

{2a. The Commission may adopt implementing acts specifying **laying down** the techniques authorised in the processing of ~~specific~~ food products.}

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).}

Article 13a

Production rules for processed feed

1. Operators producing processed feed shall in particular comply with the detailed production rules set out in Part IVa of Annex II.

²⁹ ~~A list T18~~

2. In order to ensure quality, traceability and compliance with this Regulation as regards organic processed feed production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 ~~{amending by adding to}~~ the production rules for processed feed as regards:

[...]

(b) ~~{precautionary and³⁰}~~ preventive measures to be taken as referred to in point 1.4 of Part IVa of Annex II;

[...]

~~{(i) — techniques used in feed processing.}~~

~~{2a. The Commission may adopt implementing acts laying down specific rules concerning the production methods and the techniques authorised in the processing of specific feed products.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).}~~

Article 14

Production rules for wine

1. Operators producing products of the wine sector shall in particular comply with the [...] **detailed** production rules set out in Part V of Annex II.

~~{2. In order to ensure quality, traceability and compliance with this Regulation as regards organic wine production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 [...]:~~

³⁰ ~~— A list T18~~

- **amending by adding oenological practices, processes and treatments that are prohibited to point 3.2 of Part V of Annex II; and**
- **amending point 3.3. of Part V of Annex II:**

Article 15

Production rules for yeast used as food or feed

1. Operators producing yeast to be used as food or feed shall in particular comply with the [...] **detailed** production rules set out in Part VI of Annex II.
2. In order to ensure quality, traceability and compliance with this Regulation as regards organic yeast production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending [...] **by adding to** the [...] **detailed** yeast production rules [...] **as laid down in point 1.3. of Part VI of Annex II.**

Article 16

Absence of certain production rules for specific livestock species and species of aquaculture animals

[...]

Pending the adoption of:

- (a) **additional general rules for other livestock species than those regulated in point 1.8. of Part II of Annex II;**
- (b) **the implementing rules referred to in paragraph 4 of Article 11 for livestock species;**

or

(c) the implementing rules referred to in paragraph 4 of Article 12 for species or group of species of aquaculture animals;

Member States may apply detailed national production rules for specific species or group of species of animals on the elements to be covered by the rules referred to in points (a) to (c), provided that these rules comply with this Regulation and that they do not prohibit, restrict or impede the placing on the market of products produced outside their territory and which comply with the requirements of this Regulation.

Article 16a

Production rules for products not falling within the categories of products referred to in

Articles 10 to 15

In order to take account of any future need to have detailed production rules for products that do not fall within the categories of products referred to in Articles 10 to 15, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending by adding to Annex II detailed production rules for those products.

Those delegated acts have to be based on the objectives and principles of organic production laid down in Chapter II and have to take into account general production rules laid down in Articles 7 to 9 and existing detailed production rules laid down for similar products. They shall lay down requirements concerning in particular allowed or prohibited treatments, practices, inputs or conversion periods:

In the absence of such detailed production rules as referred to in paragraph 1:

(a) operators shall comply with the principles laid down in Articles 4 and 5, mutatis mutandis with the principles laid down in Article 6, and with the general production rules laid down in Articles 7 to 9;

(b) Member States may apply detailed national production rules for those products referred to in paragraph 1, provided that these rules comply with this Regulation and that they do not prohibit, restrict or impede the placing on the market of products produced outside their territory and which comply with the requirements of this Regulation.

Article 17

Adoption of exceptional production rules

~~1. [...] To allow organic production to continue or recommence in the event of catastrophic circumstances [...] deriving from an ‘adverse climatic event’, animal disease, an ‘environmental incident’, a ‘natural disaster’ or a ‘catastrophic event’ as defined respectively in points (h), (i), (j), (k) and (l) of Article 2(1) of Regulation (EU) No 1305/2013 and subject to the principles laid down in Chapter II, the Commission shall adopt implementing acts laying down specific rules on how to deal with such situations, and on monitoring and reporting requirements. Those implementing acts shall provide exceptions to the production rules set out in this Regulation, for a limited period of time.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).~~

~~2. In cases where the Member State has formally recognised an event as a natural disaster as defined in point (k) of Article 2(1) of Regulation (EU) No 1305/2013 and this event makes it impossible to respect production rules laid down in this Regulation, Member States may take measures, subject to the principles laid down in Chapter II, that grant exceptions to these production rules for a limited period of time and until organic production can be re-established.~~

1. The Commission is empowered to adopt delegated acts in accordance with Article 36 in order to supplement this Regulation by providing the criteria to qualify catastrophic circumstances deriving from an 'adverse climatic event', 'animal diseases', 'environmental incident', natural disaster' or a 'catastrophic event' as defined in points (h), (i), (j), (k) and (l), respectively, of Article 2(1) of Regulation 1305/2013 [as well as any comparable situation] and by laying down specific rules including possible derogation from this Regulation on how Member States shall deal with such catastrophic circumstances if they decide to apply this Article as well as specific rules on monitoring and reporting in such cases. These criteria and rules shall be subject to the principles laid down in Chapter II.

2. In cases where a Member State has formally recognised an event as a natural disaster in accordance with Article 24(3) of Regulation 1305/2013 and this event makes it impossible to respect the production rules laid down in this Regulation, the Member State may grant exceptions to the production rules for a limited period of time and until organic production can be re-established, subject to the principles laid down in Chapter II and to any delegated act adopted in accordance with paragraph 1.

3. Member States may adopt measures in accordance with the delegated act referred to in paragraph 1 to allow the organic production to continue or recommence in the event of catastrophic circumstances.

Article 18

Collection, packaging, transport and storage

1. Organic products shall be collected, packaged, transported and stored in accordance with the rules set out in Annex III.
2. In order to ensure the integrity of organic production and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36:

- amending [...] the rules set out in **point 2 of Annex III**.
- **amending by adding to the rules set out in points 3, 4 and 6 of Annex III.**

Article 19

Authorisation of products and substances used in organic production

1. The Commission may authorise certain products and substances for use in organic production and **shall** include them in restricted lists, for the following purposes:

- (a) as **active substances to be used in** plant protection products;
- (b) as fertilisers, soil conditioners and nutrients;
- (c) **as non-organic feed material of plant, algae, animal or yeast origin or as feed material of microbial or mineral origin;**
- (d) as feed additives and processing aids;
- (e) as products for cleaning and disinfection of ponds, cages, tanks, raceways, buildings and installations used for animal production;
- (f) as products for cleaning and disinfection of buildings and installations used for plant production, including storage on an agricultural holding.
- (fa) as products for cleaning and disinfection in processing and storage facilities.**

1a. In [...] **addition**, the Commission may authorise certain products and substances for use in the production of [...] processed **organic food and of yeast used as food or feed** and **shall** include them in restricted lists, for the following purposes:

- (a) as food additives and processing aids;

(aa) as non-organic agricultural ingredients to be used for the production of organic processed food;

(b) as processing aids for the production of yeast and yeast products.

2. The authorisation of the products and substances referred to in [...] paragraph 1 for use in organic production shall be subject to the principles laid down in Chapter II and to the following criteria which shall be evaluated as a whole:

{(a) their use is ~~necessary~~ ***essential to ensure*** for sustained production and ~~essential~~ for ~~its~~ ***their*** intended use};

(b) all products and substances are of plant, **algae**, 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 point (a) of [...] paragraph 1, the following shall apply:

(i) their use is essential for the control of a pest 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, **algae**, 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 point (b) of [...] paragraph 1, their use is essential for obtaining or maintaining the fertility of the soil or to fulfil specific nutrition requirements of crops, or for specific soil-conditioning purposes;

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

(i) their use is necessary to maintain animal health, animal welfare and vitality and contribute to an appropriate diet fulfilling the physiological and behavioral needs of the species concerned or their use is necessary to produce or preserve feed because the production or preservation of feed is not possible without having recourse to such substances;

(ii) feed of mineral origin, trace elements, vitamins or provitamins shall be of natural origin, except where products or substances from such sources are not available in sufficient quantities or qualities or if alternatives are not available;

(iia) the use of non-organic feed material of plant or animal origin may be authorised only when feed material of plant or animal origin produced in accordance with organic production rules is not available in sufficient quantity;

(iib) the use of non-organic spices, herbs, and molasses may be authorised only provided that:

(i) they are not available in organic form;

(ii) they are produced or prepared without chemical solvents;

(iii) their use is limited to 1 % of the feed ration of a given species, calculated annually as a percentage of the dry matter of feed from agricultural origin.

2a. The authorisation of the products and substances referred to in [...] paragraph 1a for use in the production of [...] processed **organic food and of yeast used as food or feed** shall be subject to the principles laid down in Chapter II and to the following criteria which shall be evaluated as a whole:

(a) alternative products or substances authorised in accordance with this Article **or techniques compliant with this Regulation** are not available;

(b) it would be impossible to produce or preserve the food or to fulfil given dietary requirements provided for on the basis of the Union legislation, without having recourse to those products and substances;

(c) they are to be found in nature and may have undergone only mechanical, physical, biological, enzymatic or microbial processes, except where products and substances from such sources are not available in sufficient quantities or qualities;

(ca) the organic ingredient is not available in sufficient quantity.

2b. The authorisation of the use of **{chemically synthesised products and substances}** referred to in paragraphs 1 and 1a shall be strictly limited to cases where the use of external inputs referred to in point (f) of Article 4 would contribute to unacceptable [...] impacts **on the environment.**

3. In order to ensure quality, traceability and compliance with this Regulation as regards organic production in general and the production of processed organic food in particular, and adaptation to technical developments, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 [...] **amending paragraphs 2 and 2a by adding further** criteria for the authorisation or withdrawal of the authorisation of products and substances referred to in **paragraphs 1 and 1a** for use in organic production in general and in the production of [...] processed **organic** food in particular [...].

4. Where a Member State considers that a product or substance should be added to, or withdrawn from the lists of authorised products and substances referred to in paragraphs 1 and 1a, or that the specifications of use mentioned in the production rules should be amended, the Member State concerned shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the other Member States **{and is publicly available, subject to legislation on data protection.}**

~~{Requests for amendment or withdrawal shall be published by [...] the Commission with the consent of the owner of the file.}~~

4a. The Commission shall review regularly the lists referred to in this Article. The list of non-organic ingredients shall be reviewed at least once a year.

5. The Commission shall adopt implementing acts authorising or withdrawing the authorisation of products and substances **referred to in paragraphs 1 and 1a** that may be used in organic production in general and [...] in the production of processed organic food in particular, and establishing the procedures to be followed for the authorisation and the lists of those products and substances and, where appropriate, their description, compositional requirements and conditions for use. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 19aa

Authorisation of non-organic agricultural ingredients for organic processed food by Member States

1. Where it is necessary in order to ensure access to certain agricultural ingredients and where such ingredients are not available in sufficient quantity in organic form, upon request of an operator, a Member State may provisionally authorise on its territory the use of non-organic agricultural ingredients for the production of organic processed food for a period of maximum 6 months. The authorisation granted shall apply to all operators in that Member State.

Member States shall immediately notify to the Commission and other Member States via a computer system enabling the exchanges of documents and information made available by the Commission any authorisation granted for their territories.

The Member State may prolong the authorisation provided for in paragraph 1 for a maximum of two times for 6 months each, if no Member State has objected to the notification in the system referred to in subparagraph 2 by indicating that there is sufficient quantity available.

Control authorities or control bodies recognised in accordance with Article 29 (1) may grant for a maximum of 6 months a provisional authorisation as referred to in subparagraphs 1 and 3 to operators in Third countries that request such an authorisation and that are subject to their controls when the conditions of those subparagraphs are fulfilled in the third country concerned. The authorisation may be prolonged for a maximum of two times 6 months each.

2. Where, after two prolongations, it is considered, on the basis of objective information, that the availability of the said ingredient in organic form remains insufficient to meet the qualitative and quantitative needs of operators; Member States may make a request in accordance with paragraph 4 of Article 19 to the Commission. †

Article 19a

Collection of data concerning the availability on the market of organic and in-conversion plant reproductive material, organic animals and organic aquaculture juveniles

1. Each Member State shall ensure that a regularly updated database is established for the listing of the organic or in-conversion plant reproductive material {except seedlings}, including seed potatoes which is available on its territory.

~~In order to promote and facilitate the use of organic reproductive material *[which is inherently adaptable to local conditions and to organic production]* and to improve transparency by providing information on its availability *[, including its adaptability to local conditions and to organic production]*, each Member States shall have *in place* ~~the~~ *systems in place* that allow operators who market that organic *or in-conversion* material and who are able to supply it in sufficient quantities and within a reasonable time period, to make public on a voluntary basis, free of charge, together with their names and contact details, the following data:~~

~~(a)~~ the organic and in-conversion plant reproductive material except seedlings, ~~such~~ as heterogeneous material, seeds and propagating material suitable for organic production, including seed potatoes, which are available; the quantity in weight of those materials and the period of the year of its availability. That organic reproductive material shall be listed using at least the Latin scientific name;

~~(b)~~ ~~the organic animals for the purposes of the application of the derogations provided for in point 1.3.5a, including information, if relevant to the different species of animals, as regards the breeds and strains of [livestock], [adapted to organic farming in accordance with point 1.3.4 of Part II of Annex III] available, including the landraces, [parentage line], the age of the animals, and the number of breeding animals categorised by sex.~~

~~(b)~~ ~~the organic animals for which derogation can be provided in accordance with point 1.3.5~~ca~~ of Annex II, part II ;the number of available animals categorised by sex; information, if relevant, relating to the different species of animals as regards the breeds and strains available; the races, the age of the animals and any other relevant information.~~

(d) the organic aquaculture juveniles available on its holding and its production capacity for each aquaculture species and their health status in accordance with Council Directive 2006/88/EC³¹ ;

~~3.~~ ~~Member States may also set up systems which allow operators who market breeds and strains adapted to organic farming in accordance with point 1.3.4 of Part II of Annex II or organic pullets, and who are able to supply these animals in sufficient quantities and within a reasonable time period to make public the relevant data on a voluntary basis, free of charge, together with name and contact details.~~

³¹ Council Directive 2006/88/EC on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals) – (OJ EU L328; 24.11.2006, page 14)

~~XX. Operators who including material or animals in the systems referred to in the 1st subparagraph ~~(paragraphs 2 and 3)~~ shall ensure that the information is updated regularly and that the information is withdrawn from the lists once the material or animals are no longer available.~~

~~2a. For the purpose of paragraphs 1, 2, and 3, Member States may continue to use already existing seeds databases and systems for livestock and aquaculture juvenile Member States may continue to use already existing relevant information systems.~~

2b. The Commission shall make public the link to each of the national databases or systems in a Commission dedicated website, thus allowing users to have access to such a data throughout the Union.

~~6. The Commission may adopt implementing acts~~

~~(a) to provide technical details for establishing and maintaining the databases referred to in paragraph 1 and the systems referred to in paragraph 2;~~

~~(b) to provide specifications as regards the collection of data referred to in paragraph 1 and 2;~~

~~(c) to provide specifications as regards the conditions for registration referred to in paragraph 4; and~~

~~(d) to provide details as regards the information to be provided by Member States in accordance with Article 35 (2).~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37.~~

~~2. The Commission shall adopt implementing acts to provide technical details concerning the collection of data referred to in this Article.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37.~~

[...]

Article XX

Obligations ~~of~~ and actions ~~by the operator~~ in the event of suspicion of non-compliance

Where an operator suspects that a product he has produced, prepared, imported or that he has received from another operator is not in compliance with the requirements of this Regulation, that operator shall:

(a) separate and identify the product(s) concerned;

~~[(ab) check whether the suspicion can be substantiated;]~~

(b) ~~[withdraw or]~~ not place the product(s) concerned on the market as organic or in-conversion product(s) ~~[and not use them in organic production]~~ ~~[, unless the suspicion can be eliminated; during the investigation referred to in paragraph 1 (a) of Article 26e [and consider [if appropriate] withdrawing the products from the market]. below in paragraph 2(a) is finalised];~~

~~[(c) check whether the suspicion can be substantiated;]~~

(d) ~~[when substantiated or when the suspicion cannot be eliminated,]~~ immediately inform the relevant competent authority or, as appropriate, the relevant control authority or control body with, where appropriate, available elements;

(e) fully cooperate in verifying and identifying the reasons for the suspected non-compliance with the relevant competent authority or, as appropriate, with the relevant control authority or control body.

~~[2. — Where a competent authority, or where appropriate a control authority or control body suspects or receives substantiated information that an operator intends to use or to place on the market a product that may not be in compliance with the requirements of this Regulation but bearing a reference to the organic production method, or is informed by an operator in accordance with paragraph 1:~~

~~(a) it shall immediately carry out an official investigation in accordance with Regulation (EU) No XXX/XXX (Official controls Regulation) to be completed as soon as possible, within a reasonable period of time, taking into account the durability of the product and the complexity of the case with a view to verify compliance with the requirements of this Regulation;~~

~~(b) it shall provisionally prohibit the placing on the market of the products concerned as organic or in-conversion products and their use in organic production while expecting the results of the investigation referred to in paragraph 2(a). Before taking such a decision, the competent authority, or where appropriate, the control authority, or control body shall allow the operator to comment.~~

~~3. In case the results of the investigation referred to in paragraph 2(a) do not show any non-compliance affecting the organic integrity, the operator shall be allowed to use the products concerned or to place them on the market as organic or in-conversion products.~~

~~4. Member States shall take whatever measures and sanctions are required to prevent fraudulent use of the indications referred to in Chapter IV of this Regulation.~~

~~†~~Article 20a

~~{Precautionary measures to avoid the presence of non-authorised products and substances}~~

1. In order to avoid contamination with products and substances that are not authorised to be used in organic production in accordance with Article 7(1)(b) first subparagraph, operators shall take the following precautionary measures at all stages of production, preparation and distribution:

(a) Put in place and maintain proportionate and appropriate measures to identify risks of contamination of organic production and products with non-authorised products and substances, including systematic identification of critical procedural steps;

(b) Put in place and maintain proportionate and appropriate measures to avoid risks of contamination of organic production and products with non-authorised products and substances;

(c) Regularly review and adjust such measures; and,

(d) Comply with other relevant requirements of this Regulation that ensure the separation of organic and non-organic products.

3. Where an operator suspects ~~due to~~ the presence of a product or substance that is not authorised in organic production pursuant to Article 7(1)(b), first subparagraph in a product that is intended to be used or marketed as an organic or in-conversion product, ~~is not in compliance with the requirements of this Regulation,~~ ~~that the~~ operator shall:

(a) separate and identify the product(s) concerned;

~~(b) check whether the suspicion can be substantiated;~~

(b) not place the product(s) concerned on the market as an organic or in-conversion product(s) and not use it in organic production ~~until the investigation referred to in Article 20b/ paragraph 4 is finalised;~~ unless the suspicion can ~~not~~ be eliminated;

~~(c) check whether the suspicion can be substantiated;~~

(d) ~~when substantiated or when the suspicion cannot be eliminated,~~ immediately inform the relevant competent authority or, as appropriate, the relevant control authority or control body with, where appropriate, available elements;

(e) fully cooperate in verifying and identifying the reasons for the presence of non-authorised products and substances with the relevant competent authority or, as appropriate, the relevant control authority or control body.

4. The Commission ~~shall~~may adopt implementing acts laying down uniform rules specifying:

- the procedural steps to be followed by operators as referred to in paragraph 3(a) to (e) ~~and relevant documentation to be provided~~;
- the proportionate and appropriate measures to be adopted and reviewed by operators to identify and avoid risks of contamination as referred to in paragraph {1} (a) to (c) ;
- the details and format of the information to be transmitted by Member States to the Commission and other Member States as referred to in paragraph 6 of Article 20b}.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).}

Article 20b

Measures to be taken in cases of the presence of non-authorised products and substances}

4. When a competent authority, or where appropriate, a control authority or control body, receives substantiated information about the presence of products or substances that are not authorised in organic production pursuant to Article 7(1)(b) first subparagraph, or is informed by an operator in accordance with ~~Article 20a~~ paragraph {3} or detects such products or substances in an organic or an in-conversion product:

- (a) it shall carry out immediately an ~~official~~ investigation ~~in accordance with the Regulation (EU) No XXX/XXXX [Official controls Regulation] to be completed as soon as possible, within a reasonable period of time, taking into account the durability of the product and the complexity of the case, with a view to determine the sources and the cause of contamination in view of verifying compliance with Article 7(1)(b) and paragraph {1} of Article 20a.~~

(b) it shall provisionally prohibit the placing on the market of the products concerned as organic or in conversion products and their use in organic production while expecting the results of the investigation as referred to in (a);

~~[4a.—When the competent authority, for where appropriate, a control authority or control body, has not established within the reasonable period of time referred to in paragraph 4(a) that the operator concerned:~~

~~—————has used the products or substances not authorised in organic production pursuant to Article 7(1)(b) first subparagraph or;~~

~~—————has failed to take the precautionary measures referred to in paragraph 2[1];~~

~~the [competent authority shall authorise the] operator [may to] market the product as an organic or in-conversion product and use it in organic production.]~~

5. When the competent authority, for where appropriate, a control authority or control body, has established that the operator concerned:

(a) has used products or substances not authorised in organic production pursuant to Article 7(1)(b) first subparagraph or:

(b) has not taken the precautionary measures referred to in paragraph 1 of Article 20a;
or

(c) has not taken measures pursuant to relevant previous requests from the competent authorities, control authorities or control bodies,

the product shall not be marketed as an organic or in-conversion product or used in organic production.

6. The operator concerned shall be allowed to give his comments on the results of the investigation. The competent authority, or where appropriate, the control authority or control body, shall keep records of the investigation carried out. [Where required, the operator concerned shall take the necessary corrective measures to avoid future contamination.]

~~6a. By way of derogation to paragraphs 4a, products in which the presence of more than two products or substances used as plant protection product, but not authorised to be used in organic production pursuant to Article 7(1)(b), is detected above twice the limit of determination, shall not be marketed as an organic or in-conversion product or used in organic production.~~

7. ~~Two/Five/ Four~~ years after the date of application of this Regulation, the Commission shall present a report to the European Parliament and the Council on the state of play of implementation of this article, ~~and on the presence of products and substances not authorised in organic production pursuant to Article 7(1)(b) first subparagraph~~ and on the assessment of national rules referred to in subparagraph 2. This report may be accompanied, if appropriate, by a legislative proposal to provide for further harmonisation ~~establishing the levels of unauthorised products or substances not acceptable for organic products and the systems for compensating operators for losses in connection with unavoidable contamination.~~

~~Member States that have, on 31 December 2015, having in place rules providing for that products containing non-authorised products and substances above a certain level cannot not to be marketed as organic, may continue to apply these rules until 31 December 2024 provided that these rules do not prohibit, restrict or impede the placing on the market as organic of products produced in other Member States in compliance with the requirements of this Regulation. Member States who apply this provision shall inform the Commission without delay.~~

8. The results of the investigations referred to in paragraph 4 shall be documented by competent authorities, together with any measures taken with a view to formulating best practices and further measures to avoid the presence of products and substances not authorised in organic production pursuant to Article 7(1)(b).

Member States shall make this information available to the other Member States and to the Commission via a computer system enhancing exchanges of documents and information made available by the Commission.

9. Member States ~~{may/shall}~~ take appropriate measures on their territory to avoid the unintended presence of non-authorised products and substances in organic agriculture. Such measures shall not prohibit, restrict or impede the placing on the market as organic or in-conversion of products produced in other Member States in compliance with the requirement of this Regulation. Member States which apply this provision shall inform the Commission and the other Member States without delay.

10. The Commission ~~{may/shall}~~ adopt implementing acts laying down uniform rules specifying the methodology on detection and evaluation of the presence of non-authorised products and substances to be applied by control authorities and control bodies.;

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

11. By 31 March of each year, Member States shall transmit by electronic way to the Commission the relevant information, including information collected at border control posts, relating to the previous year concerning the nature of contamination detected, and in particular the cause, the source, the level of contamination and the volume and nature of products contaminated. This information on findings of non-authorised products and substances shall be collected by the Commission ~~in~~ through the ~~{database/information~~ computer system} as referred to in Article ~~{26xxx}~~ and shall be used to facilitate the formulation of best practices to avoid contamination.

Chapter IV

Labelling

Article 21

Use of terms referring to organic production

1. For the purposes of this Regulation, a product shall be regarded as bearing terms referring to organic production 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 this Regulation. In particular, the terms listed in Annex IV, their derivatives or diminutives, such as ‘bio’ and ‘eco’, alone or combined, may be used throughout the Union and in any language listed in that Annex for the labelling and advertising of products **referred to in Article 2(1)** which comply with this Regulation.

2. For the products referred to in Article 2(1), the terms referred to in paragraph 1 of this Article shall not be used anywhere in the Union, in any language listed in Annex IV, for the labelling, advertising and commercial documents of a product which does not comply with this Regulation.

Furthermore, any terms, including terms used in trademarks **or company names**, or practices used in labelling or advertising liable to mislead the consumer or user by suggesting that a product or its ingredients comply with this Regulation shall not be used.

2a. Plant reproductive material and food and feed products of plant origin produced during the conversion period in compliance with Article 8(4) may be labelled as in-conversion products.

OR

~~/Products of plant origin produced during the conversion period in compliance with Article 8(4) may be labelled as in-conversion products., provided that:~~

~~(a) 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;~~

~~(b) the product contains only one crop ingredient of agricultural origin;~~

~~(c) the indication is linked to the code number of the control body or control authority as referred to in Article 22 (1)(a) of this Regulation (CSL mandate 27/02/2017);~~

2b. The terms referred to in paragraph 1 and 2a 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 Union law.

~~/As regards products and substances used in crop production as plant protection products, fertilizers, soil conditioners and nutrients, authorized according to article 19, these may bear reference indicating that the product or substance is authorized for use in Organic Agriculture in accordance with this Regulation./~~

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

(a) in the sales description, **and in the list of ingredients where such a list of ingredients is mandatory according to Union legislation**, provided that:

(i) the processed food complies with the production rules set out in Part IV of Annex II **{and with the specific rules laid down in accordance with Article 13(2a)}**;

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

- (b)** only in the list of ingredients [...], **provided that:**
- (i)** less than 95% **by weight** of agricultural ingredients are organic and provided that those ingredients comply with the production rules set out in this Regulation;
 - (ii)** **the processed food complies with the production rules set out in points 1.5, ~~2.1(a), 2.2.1~~, and 2.1(c) of Part IV of Annex II and with the specific rules laid down in accordance with Article 13(2~~a~~);**
- (ba)** **in the sales description and in the list of ingredients provided that:**
- (i)** **the main ingredient is a product of hunting or fishing;**
 - (ii)** **the term referred to in paragraph 1 is clearly related in the sales description to another ingredient which is organic and different from the main ingredient;**
 - (iii)** **all other agricultural ingredients are organic;**
 - (iv)** **the food complies with points 1.5, 2.1(a), ~~2.1(b)~~, and 2.1(c) and 2.2.1 of part IV of Annex II.**

The list of ingredients referred to in points **(a)**, **(b)** **and (ba)** of the first subparagraph shall indicate which ingredients are organic. The references to organic production may only appear in relation to the organic ingredients.

[...] **The list of ingredients referred to in points (b) and (ba) of the first subparagraph** shall include an indication of the total percentage of organic ingredients in proportion to the total quantity of agricultural ingredients.

The terms referred to in paragraph 1 **used in the list of ingredients referred to in points (a), (b), and (ba) of the first subparagraph as well as** [...] the indication of the percentage referred to in **points (b) and (ba)** of the first subparagraph [...] shall appear in the same colour, identical size and style of lettering as the other indications in the list of ingredients.

~~{As regards plant varieties, the terms referred to in paragraph 1 may be used in the sales description, provided that:~~

~~(a) — the breed complies with the production rules set out in point 1.4 of Part I of Annex II; and~~

~~(b) — the term "organic breed" is used.}~~

3a. As regards processed feed, the terms referred to in paragraph 1 may be used in the sales description and in the list of ingredients provided that:

(a) the processed feed complies with the production rules set out in Parts II, III and IV of Annex II and with the specific rules laid down in accordance with Article 13(2ab**);**

(b) all ingredients of agricultural origin contained in the processed feed are organic;

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

4. In order to provide clarity for consumers and to ensure that the appropriate information is communicated to them, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 **amending [...] the list of terms set out in Annex IV, taking into account linguistic developments within the Member States, [...] **and amending by adding rules as regards labelling of products listed in Annex I to this Regulation.****

4a. The Commission may adopt implementing acts to set detailed requirements for the application of paragraph 2a. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

~~Article 21a~~

Labelling of products and substances used in crop production

Notwithstanding the scope of this Regulation as set out in Article 2(1), a product or substance used in ~~crop production~~ a plant protection product or as fertiliser, soil conditioner or nutrient authorised in accordance with Article 7 and Article 19 may bear a reference indicating that the product or substance is authorised for use in organic production in accordance with this Regulation.³²

Article 22

Compulsory indications

1. Where **products bear** terms as referred to in Article 21(1) [...], **including products labelled as in conversion in accordance to Article 21(2a):**

(a) the code number of the control authority or control body to which the operator who has carried out the last production or preparation operation is subject, shall also appear in the labelling;

(b) the organic production logo of the European Union referred to in Article 23 as regards pre-packed food as defined in point (e) of Article 2(2) of Regulation (EU) No 1169/2011 shall also appear on the packaging **except in cases referred to in Article 21 (2a), (3)(b) and (ba).**

~~2.~~ where the organic production logo of the European Union 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:³²

(a) ‘EU Agriculture’, where the agricultural raw material has been farmed in the Union;

(b) ‘non-EU Agriculture’, where the agricultural raw material has been farmed in third countries;

³² — A list T18

(c) ‘EU/non-EU Agriculture’, where a part of the agricultural raw materials has been farmed in the Union and a part of it has been farmed in a third country.

The word ‘Agriculture’ may be replaced by ‘Aquaculture’ where appropriate.

The indication ‘EU’ or ‘non-EU’ may be replaced or supplemented by the name of a country **or by the name of a country and a region** if all agricultural raw materials of which the product is composed have been farmed in that country **or region**.

For the indication ‘EU’ or ‘non-EU’ **or of the name of the country/region as referred to in subparagraph 3**, small quantities by weight of ingredients may be disregarded provided that the total quantity of the disregarded ingredients does not exceed 5% of the total quantity by weight of agricultural raw materials.

The indication ‘EU’ or ‘non-EU’ shall not appear in a colour, size and style of lettering more prominent than the name of the [...] **product**.

3. The indications referred to in paragraphs 1 and 2 of this Article and in Article 23(3) shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.

4. In order to provide clarity for consumers and to ensure that the appropriate information is communicated to them, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 [...] **amending by adding** rules on labelling [...]in paragraph 2 of this Article and in Article 23(3).

5. The Commission shall adopt implementing acts relating to the following:

(a) practical modalities as regards the **use**, presentation, composition and size of the indications referred to in point (a) of paragraph 1 and in paragraph 2 of this Article and in Article 23(3);

(b) the assignment of code numbers to control authorities and control bodies;

(c) the indication of the place where the agricultural raw materials have been farmed, in accordance with paragraph 2 of this Article and Article [...] **23(3)**.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Organic production logo of the European Union

1. The organic production logo of the European Union may be used in the labelling, presentation and advertising of products which comply with this Regulation.

The organic production logo may also be used for information and educational purposes related to the existence and advertising of the logo itself, provided that the use is not liable to mislead the consumer as regards the organic production of specific products and provided that the logo is reproduced in accordance with the rules set out in Annex V. In this case, the requirements of Article 22 (2) and point 1.7 of Annex V shall not apply.

The organic production logo of the European Union shall not be used for processed food as referred to in Article 21(3)(b) and (ba) or for in-conversion products as referred to in Article 21(2a).

2. **Except in cases referred to in second sub-paragraph of paragraph 1**, the organic production logo of the European Union is an official attestation in accordance with ~~f~~Articles 85 and 90~~g~~ of Regulation (EU) No XXX/XXXX [Official controls Regulation].

3. The use of the organic production logo of the European Union shall be optional for products imported from third countries. In addition, where that logo appears in the labelling, the indication referred to in Article 22(2) shall also appear in the labelling.

4. The organic production logo of the European Union shall follow the model set out in Annex V and shall comply with the rules set out in that Annex.

5. National and private logos may be used in the labelling, presentation and advertising of products which comply with this Regulation.

6. In order to provide clarity for consumers and to ensure that the appropriate information is communicated to them, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending the organic production logo of the European Union and the rules relating thereto set out in Annex V.

Chapter V

~~{Organic-certification}~~

Article 24

Certification system

1. Operators or groups of operators **as referred to in Article 26 [...]** who produce, prepare, **distribute** or store organic **or in-conversion** products, who import such products from a third country or export such products to a third country, or who place such products on the market, prior to placing on the market **any products as 'organic' or as 'in-conversion'** or prior to **the conversion period shall** notify their activity to the **competent authorities of the** Member State **in which their** activity is carried out **and in which their undertaking is submitted to the control system.**

In case the competent authorities have conferred their responsibilities or delegated specific official controls tasks or other official activities to more than one control authority or control body, the operators or group of operators shall indicate in the notification referred to in paragraph 1, the control authority or the control body that verifies the compliance of the activity with this Regulation and provides the certificate referred to in Article 25(0a).

2. **Operators who sell pre-packed organic products directly to the final consumer or user, provided that they do not produce, prepare or store such products other than in connection with the point of sale do not import such products from a third country or have not subcontracted such activities to another operator, are exempted from the notification obligation referred to in paragraph 1 and from the obligation to be in the possession of a certificate referred to in paragraph 0b of Article 25.**

~~*Member States may exempt from the notification obligation referred to in paragraph 1 operators who sell up to 500 kilogrammes per year, representing a turnover not exceeding 5000 Euro of unpacked organic products directly to the final consumer or user, provided that they do not produce, prepare or store such products other than in connection with the point of sale, do not import such products from a third country or have not subcontracted such activities to a third party.*~~

~~*Member States may exempt from the notification obligation referred to in paragraph 1 operators who sell unpacked organic products directly to the final consumer or user, provided that they do not produce, prepare or store such products other than in connection with the point of sale, do not import such products from a third country or have not subcontracted such activities to a third party.*~~

~~*In such a case, the operators shall inform the competent authority about their activities.*~~

3. Where operators or groups of operators subcontract any of their activities to [...] third [...] **parties**, both the operators or groups of operators and the third [...] **parties** to whom activities have been subcontracted, shall comply with paragraph 1, **except where the operator or groups of operators declares in the notification referred to in paragraph 1 that the responsibility as regards organic production remains with the operator or groups of operators and is not transferred to the subcontractor. In such cases the compliance of the subcontracted activities with this Regulation is verified by the competent authorities in the framework of the control of the operators or groups of operators who have subcontracted their activities.**

4. Member States shall designate an authority or approve a body to receive the notifications referred to in paragraph 1.

5. Operators, [...] groups of operators, **and subcontractors** shall keep records on the different activities they engage in, in accordance with this Regulation.

6. [...] **Member States** shall keep updated [...] **lists** containing the names and addresses of operators and groups of operators that have notified their activities in accordance with paragraph 1 and shall make public **in an appropriate manner, including by means of links to a single internet website, a comprehensive list of this data**, together with the information relating to their [...]certificates as referred to in Article 25 (0a).[...] **Member States** shall respect the requirements of the protection of personal data under Directive 95/46/EC of the European Parliament and of the Council.

7. Member States shall ensure that **any operator or group of operators who complies with this Regulation, and who, if a fee is collected in accordance with Articles ~~78~~ 76 and ~~79~~ 77 of Regulation (EU) No XX/XXXX (Official Controls Regulation), pays a reasonable fee covering the cost of controls, is entitled to be covered by the control system and that fees that may be collected** are made public.

8. In order to ensure the effectiveness, efficiency and transparency of the organic production and labelling system, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 [...] **amending** the requirements for keeping records **laid down in Annex II** [...].

9. The Commission may adopt implementing acts to provide details and specifications regarding:

[...]

- [...] **the format and technical means of the notification referred to in paragraph 1,**
- **the modalities of the publication of the lists referred to in paragraph 6 and,**
- **the procedures and modalities of publication of the fees referred to in paragraph 7.**

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Certificate

0a. **Competent authorities or, where appropriate, control authorities or control bodies shall provide a certificate to any operator or group of operators that have notified their activity in accordance with Article 24(1) and comply with this Regulation. The certificate shall certify that the notified activity is in compliance with this Regulation and shall be issued in accordance with the model set out in Annex Vd.**

0b. **~~Without prejudice to paragraph 5b³³ and to Article 24(2)~~, operators and group of operators shall be in possession of a certificate as referred to in paragraph 0a prior to the placing on the market of products referred to in Article 2(1) ~~as organic or in-conversion³⁴~~.**

0c. **~~The certificate referred to in this article is an official certificate attestation within the meaning of Articles 86(1)(a) ~~85 and 86~~ of Regulation (EU) No XXX/XXX (Official controls Regulation).~~³⁵**

0d. **The certificate, issued in electronic form wherever possible, shall at least allow the identification of the operator or group of operators including the list of the members, the category of products covered by the certificate and its period of validity.**

[...]

3. **Operators and groups of operators shall not be entitled to be provided with a [...] certificate by different [...] control bodies for activities carried out in one Member State, [...] as regards the same category [...] of products, including when those operators and groups of operators engage in different stages of production, preparation and distribution.**

³³ — A list T18

³⁴ — A list T18

³⁵ — A list T18

4. Members of a group of operators shall not be entitled to be provided with an individual [...] certificate for any of the activities covered by the certification of the group.

5. Operators shall [...] verify the [...] certificate of operators that are their suppliers.

5a. The categories of products referred to in paragraph 0d and 3 are the following:

- **unprocessed plants and plant products, including seed and other plant reproductive material;**
- **livestock and unprocessed livestock products;**
- **algae and unprocessed aquaculture products;**
- **processed agricultural products, including aquaculture products, for use as food;**
- **feed;**
- **wine,**
- **other products listed in Annex I to this Regulation or not covered by the previous categories.**

~~5b. Member States may exempt from the obligation to be in the possession of a certificate, as referred to in paragraph 0b, operators who sell directly to the final consumer or user-unpacked organic products other than feed:~~

- **~~up to ~~1000/5000~~ kilogrammes per year, or~~**
- **~~representing an annual turnover not exceeding ~~10 000/20 000~~ Euro on unpacked organic products or,~~**
- **~~with a potential certification cost not exceeding ~~1/2~~% of the total turnover on unpacked organic products,~~**

provided that those operators do not produce, prepare or store such products other than in connection with the point of sale, do not import such products from a third country or have not subcontracted such activities to a third party.

In case Member States decide to exempt the operators referred to in the first sub paragraph, they may set lower limits than those set in the first sub-paragraph.

Member States shall inform the Commission and the other Member States of their decision to exempt operators as referred to in the first sub-paragraph and on the limits up to which such operators are exempted.[†]

6. In order to ensure the effectiveness, efficiency and transparency of the organic production and labelling system, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending [...] **the model of the certificate set out in Annex Vd.**

6a. The Commission shall adopt implementing acts to provide details and specifications regarding the form of the certificate referred to in paragraph 0a and the technical means by which it is issued.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 26

Group of operators

1. Each group of operators shall:

- (a) only be composed of farmers or operators producing algae or aquaculture animals and who in addition may be engaged in processing, preparation or marketing of food or feed;**

- (b) only be composed of members:
 - (i) of which the individual certification cost represents more than 2% of its turnover or standard output of organic production ~~and whose turnover of organic production is not more than 25 000 € or whose standard output from of organic production is not more than 15 000 Euro per year~~; or
 - (ii) which have each holdings of maximum:
 - a) 5 hectares; or
 - b) 0.5 hectares, in the case of ~~covered crops~~ greenhouses or
 - c) 15 hectares, exclusively in the case of permanent grassland;
- (c) be established in a Member State or a third country;
- (d) have legal personality;
- (e) the production activities of the members of the group take place in geographical proximity to each other;
- (f) set up a joint marketing system for the ~~organic~~ products produced by the group; and
- (g) establish a system for internal controls **comprising** a documented set of control activities and procedures, in accordance with which an identified person or body is responsible for verifying compliance with this Regulation of each member of the group.

2. Deficiencies in the set-up or functioning of the system for internal controls referred to in paragraph 1, in particular as regards failures to detect or address non-compliance by individual members of the group of operators that affect the integrity of organic and in conversion products, [...] **shall** result in the withdrawal of the [...] **certificate referred to in Article 25** for the whole group.

3. In order to ensure the effective and efficient functioning of the certification of a group of operators, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending[...] paragraphs 1 and 2 by adding provisions in particular as regards:

~~{~~ the responsibilities of the individual members of a group of operators,~~}~~

~~— the composition and dimension of a group of operators~~

- ~~{~~ **as well as the criteria to determine the geographical proximity of the members of the group *such as the sharing of facilities or sites,***~~}~~

- [...]

~~— the conditions for participation in a group of operators,~~

- the set-up and functioning of the ~~group's system for~~ internal controls system, including the scope, content and frequency of the controls to be carried out **and the criteria to [...] *identify qualify deficiencies in the set-up or functioning of the system for internal controls.***

4. The Commission may adopt implementing acts [...] **laying down specific rules** concerning:

- ~~{~~ **uniform application of paragraph 1, point (e);**~~}~~

- ~~{~~ the composition and dimension of a group of operators **as well as the criteria to determine the geographical proximity of the members of the group;**~~}~~

- ~~the conditions for participation in a group of operators, including regarding the categories of products they produce;~~

- ~~{~~ the set-up and functioning of the group's system for internal controls, including the scope, content and frequency of the controls,~~}~~

- the documentation and record keeping systems, the system for internal traceability and the list of operators;

- ~~the responsibilities and obligations of the individual members of a group of operators and}~~

- the exchange of information between a group of operators and the competent authority or authorities, control authorities or control bodies, and between the Member States and the Commission.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37 (2).]

Chapter Va

Official controls and other official activities

Article 26a

Relationship with Regulation (EU) No XX/XXX (Official Controls Regulation) and additional rules for official controls and other official activities in relation to organic production and labelling of organic products

The specific rules of this Chapter shall apply, in addition to the rules laid down in Regulation (EU) No XX/XXX (Official Controls regulation), ~~in relation to~~ **on** official controls and other official activities performed to verify, at all stages of production, preparation and distribution throughout the process, that products as referred to in Article 2(1) have been produced in compliance with the requirements laid down in this Regulation.

Article 26b

Additional rules on official controls and on action to be taken by the competent authorities

1. Official controls performed in accordance with Article ~~8~~ **9** of Regulation (EU) XX/XXXX (Official Controls Regulation) for the verification of compliance with the requirements laid down in this Regulation shall:
 - a) include, in particular,
 - (i) the verification of the application by operators of preventive and precautionary measures, as referred to in Article 7 (1)(cb) ~~and in 20a~~ of this Regulation, at all stages of production, preparation and distribution;

(ii) in the cases where the holding includes non-organic and/or in-conversion production units, the verification of the records and of the measures or procedures or arrangements in place to ensure the clear and effective separation between organic, in-conversion and non-organic production units, between products produced by the organic, in-conversion and/or non-organic production units, and of the substances and products used for organic and non-organic production units; such verification shall include checks on parcels for which a previous period was recognised retroactively as part of the conversion period and checks on the non-organic production units;

(iii) in the cases where organic and non-organic products are collected simultaneously by operators, or prepared or stored in the same preparation unit or area or premise, or transported to other operators or units, the verification of the records and of the measures or procedures or arrangements in place to ensure that operations are carried out separated by place or time, that suitable cleaning measures and, as appropriate, measures to prevent substitution of products are implemented, that organic products are identified at all times and stored, before and after the preparation operations, separated by place or time from non-organic products;

~~/(xx) the set-up and functioning of the internal control system of groups of operators;/(~~

(iv) in the cases where operators are exempted from **the notification obligation as provided for in Article 24(2), and where operators are exempted from the obligations to be in the possession of a certificate** as provided **for** in Article 24(2) **25(5b)new** of this Regulation, the verification that the requirements for the exemption are fulfilled **~~/(and the verification of the products sold by these operators;/(~~**

(b) be performed throughout the entire production process at all stages of production, preparation and distribution on the basis of the likelihood ~~[or suspicion]~~ of non-compliance with the rules laid down in this Regulation, which shall be determined taking into account, in addition to the elements referred to in Article 8 **2** of Regulation (EU) No XX/XXX (Official Controls Regulation), in particular the following elements:

- (i) the type, size and structure of the operators and groups of operators;
- (ii) the length of time during which operators and groups of operators have been in organic production, preparation and distribution;
- (iia) the results of the controls performed in accordance with this Article;
- (iii) the point in time relevant for the activities carried out;
- (iv) the product categories;
- (v) the type, quantity and value of products and their development over time;
- (vi) the possibility of commingling of products or contamination with unauthorised products or substances;
- (vii) the application of derogations or exceptions to the rules by operators and groups of operators;
- (viii) the critical points for non-compliance and likelihood of non compliance at all stages of production, preparation and distribution **of organic products;**

(ix) subcontracting activities.

(c) In any case, all operators and groups of operators ~~*with the exception of those referred to in Articles 24(2) and 25(5b)*~~ shall be subject to a verification of compliance at least once a year.

The verification of compliance shall imply a physical on-the-spot inspection except when operators and groups of operators comply with the following conditions:

- (i) the previous controls of the operator or group of operator concerned have not revealed any ~~serious~~ non-compliance affecting the [integrity] of organic **or in-conversion products** during at least three consecutive years; and

(ii) the operator or groups of operators concerned have been assessed on the basis of the elements referred to in point b) and in Article 8 ~~9~~ of Regulation (EU) No XX/XXX (Official Controls Regulation) as presenting low likelihood of non-compliance.

In this case, the period between two physical on-the-sport inspections shall not exceed 24 months.

(d) be performed in accordance with Article 9 (4) of Regulation (EU) No XXX/XXX (Official Controls Regulation);

(e) ensure that a minimum percentage of all official controls of operators or group of operators are carried out without prior notice;

(f) ensure that a minimum percentage of additional controls to those referred in paragraph (c) are carried out;

(g) be carried out by taking a minimum number of samples as referred to in Article 14(h) of Regulation (EU) No XXX/XXX (Official Controls Regulation).

~~(h) ensure that a minimum number of operators that are members of a group of operators are controlled in the framework of the verification of compliance referred to in point (c).~~

2. The delivery or the renewal of the certificate referred to in Article 25(0a) shall be based on the results of the verification of compliance as described in ~~this~~ paragraph ~~1~~ .
3. The written record to be drawn up on each official control performed to verify compliance with the rules laid down in this Regulation in accordance with paragraph ~~2~~ 1 of Article ~~12~~ 13 of Regulation (EU) XX/XXXX (Official Controls Regulation) shall be countersigned by the operator or groups of operators **to confirm the receipt of that written record.**
4. Paragraph ~~2~~ 1 of Article ~~12~~ 13 of Regulation (EU) XX/XXX (Official Controls Regulation) shall not apply to the audits and inspections carried out by competent authority/ies in the context of their supervisory activities over control bodies to which specific official control tasks and other official activities were delegated.

5. ~~In order to support the performance of official controls and other official activities to verify compliance with the requirements laid down in this Regulation, the Commission shall be empowered to adopt delegated acts in accordance with Article 36:~~

~~(a) supplementing this Regulation by laying down rules on the documentation to be kept, and on declarations and other communications to be made by operators and groups of operators in relation to official controls, as well as the practical measures to be taken to ensure compliance with this Regulation;~~

(b) supplementing this Regulation by laying down specific criteria and conditions for the performance of official controls aimed at ensuring the traceability at all stages of production, preparation and distribution, and compliance with the requirements laid down in this regulation, as concerns:

(i) checks of documentary accounts;

(ii) controls performed on specific categories of operators

(iii) where appropriate, the time period within which, and the particular premises or area on which, the controls provided for in this Regulation are to be performed, including the physical on-the-spot inspection referred to in paragraph 1(c),

~~(e) supplementing this Regulation by laying down specific arrangements for the performance of the controls of groups of operators;~~

(d) amending point (b) of paragraph 1 by laying down additional elements based on practical experience.]

6. The Commission may adopt implementing acts to specify:

(a) the minimum percentage of all official controls of operators or groups of operators that have to be carried out without prior notice referred to in point (e) of paragraph 1;

(b) the minimum percentage of additional controls referred to in point (f) of paragraph 1;

(c) the minimum number of samples referred to in point (g) of paragraph 1;

~~(d) the minimum number of operators that are members of a group of operators referred to in point (h) of paragraph 1.~~

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

~~Article 26ba~~

Additional rules on actions to be taken by the operators and group of operators

1. In addition to the obligations laid down in Article 15 of Regulation (EU) No XXX/XXX (Official Controls Regulation), operators and groups of operators shall

(a) keep documentation to demonstrate compliance with the requirements of this Regulation;

(b) make all necessary declarations and other communications to support official controls;

(c) take relevant practical measures to ensure compliance with the requirements of this Regulation;

(d) provide, in form of a declaration to be signed and updated as necessary:

(i) the full description of the organic and/or in-conversion production unit and of the activities to be performed in accordance with this Regulation;

(ii) the relevant practical measures to be taken to ensure compliance with the requirements of this Regulation;

(iii) an undertaking accepting:

- in the event of a suspicion of non-compliance or of an established non-compliance affecting the integrity of the products, to inform in writing and without due delay buyers of the products and to exchange relevant information with the competent authority, and where appropriate, with the control authority or control body;
- the transfer of the control file in case of change of control authority or control body or, in case of withdrawal from organic production, the keeping of the control file for at least five years by the last control authority or control body;
- in the event of withdrawal from organic production to immediately inform the competent authority or the authority or body designated according to the provisions of Article 24(4);
- in case subcontractors are checked by different control authorities or control bodies the exchange of information among these authorities or bodies.

2. The Commission may adopt implementing acts to provide details and specifications regarding:

(a) the documentation to demonstrate compliance with the requirements of this Regulation;

(b) all necessary declarations and other communications to support official controls;

(c) the relevant practical measures to ensure compliance with the requirements of this Regulation.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2). †

Article 26c

Additional rules on the delegation of ~~specific official controls tasks~~ certain tasks related to official controls and other official activities

1. Competent authorities may delegate to control bodies specific official control tasks and other official activities only if the following conditions, in addition to those set out in Chapter III of Regulation (EU) No XX/XXX (Official Controls Regulation), are complied with:

(a) the delegation contains a detailed description of the delegated control tasks and other official activities, including reporting and other specific obligations, and of the conditions under which the control body may carry them out. In particular the control body shall submit to the competent authorities for prior approval:

(i) its risk assessment procedure, determining in particular the basis for the intensity and frequency of the verification of compliance of the operators and groups of operators and established on the basis of the elements referred to in Article ~~8 2~~ of Regulation (EU) No XX/XXX (Official Controls Regulation) and of Article 26b of this Regulation, to be followed for the performance of official controls on operators and groups of operators

(ii) the standard control procedure in place, containing a detailed description of the control measures that the control body undertakes to apply to operators and groups of operators subject to its controls;

(iii) a list of measures, in conformity with the ~~measures laid down by competent authorities~~ common catalogue as referred to in Article 26ca, to be applied to operators and groups of operators in case of ~~the establishment, likelihood, or suspicion of non-compliance~~ established non-compliance as well as in case of suspicion of non-compliance;

(iv) the arrangements for effective monitoring and reporting on the official control tasks and other official activities performed on operators and groups of operators.

Any subsequent amendment of the elements referred to in points (i) to (iv) shall be notified by the control body to the competent authority.

(b) competent authorities have procedures and arrangements in place to ensure the supervision of control bodies, including the verification of the effectiveness, independence and objectiveness of the way in which the delegated tasks are carried out, in particular as regards the intensity and frequency of the verification of compliance.

(c) competent authorities organise audits of the control bodies to whom they have delegated official control tasks and other official activities according to Article 33(a) of Regulation (EU) No XXX/XXX at least once a year.

1a. By way of derogation from Article 31(3) of Regulation (EU) No XXX/XXX (Official Controls Regulation), Competent Authorities may delegate to a control body the decision concerning their tasks provided for in point (b) of Article 138(1) and in Article 138(2) and (3) of that Regulation.

2. For the purpose of Article ~~26(1)(b)(iv)~~ **29(b)(iv)** of Regulation (EU) No XX/XXX (Official Controls Regulation), the relevant standard for the delegation of specific official control tasks and other official activities to verify compliance with this Regulation in the area covered by this Regulation is the most recently notified version of the international harmonised standard ‘General requirements for bodies operating product certification systems’, the reference of which has been published in the Official Journal of the European Union.

3. Competent authorities shall not delegate to control bodies:

~~(a) specific official control tasks or other official activities to natural persons;~~

(a) the supervision and audit of other control bodies or control authorities;

(b) the possibility to grant derogations except for the use of plant reproductive material not obtained from organic production;

(c) the reception of the notification of the activity by operators or groups of operators, as referred to under Article 24(1) of this Regulation

(d) the assessment of the likelihood of non-compliance with the provisions laid down in this Regulation determining the frequency rate of the physical checks to be performed on organic consignments prior to their release for free circulation into the Union according to Article ~~52~~ **54** of Regulation (EU) No XX/XXX (Official Controls Regulation).

(e) the establishment of the common catalogue of measures as referred to in Article 26ca.

3a. Competent authorities shall not delegate to natural persons tasks related to official controls and other official activities.

4. Competent authorities shall ensure that information received from control bodies on the basis of Article ~~31~~ 32 of Regulation (EU) No XX/XXX (Official Controls Regulation) and information on the measures applied by control bodies in case of established or likely non-compliance is collected and used by the competent authorities in order to supervise the activities of those controls bodies.

5. In case of full or partial withdrawal of the delegation of specific official control tasks and other official activities in accordance with Article ~~32~~ 33 of Regulation (EU) No XX/XXX (Official Controls), competent authorities shall decide on the validity of the certificates beyond the date of the decision on partial or full withdrawal issued by the control bodies concerned before the date of that partial or full withdrawal and shall inform the operators.

6. Without prejudice to Article ~~32~~ 33 of Regulation (EU) No XX/XXX (Official Controls Regulation), competent authorities may, before fully or partly withdrawing the delegation of official control tasks and other official activities in the cases referred to in **Article ~~32~~ 33**, fully or partly suspend that delegation:

a) for a time period that shall not exceed 12 months and during which the control body shall take action to remedy shortcomings identified during audits and inspections or address non-compliances for which information is exchanged with other control authorities and control bodies, competent authorities as well as with the Commission according to Article 26e; or

b) for the time period during which accreditation as referred to in Article ~~26(1)(b)(iv)~~, 29(b)(iv) of Regulation (EU) No XX/XXX (Official Controls Regulation) and Article 26c (2) of this Regulation is suspended.

In case of suspension of the delegation on official controls and other official activities, control bodies concerned shall not issue organic certificates for the parts for which the delegation has been suspended. Competent authorities shall decide on the validity beyond the date of suspension of the certificates issued before the partial or full suspension and shall inform the operators concerned on this decision.

Without prejudice to Article ~~32~~ 33 of Regulation (EU) No XX/XXX (Official Controls Regulation), the competent authorities shall lift the suspension of the delegation of official control tasks and other official activities as soon as possible when the control body has taken action to remedy the shortcomings or non-compliances referred to under point a) of the first subparagraph or when the accreditation body has lifted the suspension of the accreditation referred to under point b) of the first subparagraph.

7. Where a control body to whom competent authorities have delegated specific official control tasks or other official activities has also been recognised by the Commission in accordance with Article 29(1) of this Regulation for carrying out control activities in third countries, and the Commission intends to withdraw or has withdrawn the recognition of this control body, competent authorities shall organise audits and inspections on the control body as regards its activities in the Member State(s) concerned, in accordance with Article ~~32~~ 33 of Regulation (EU) No XX/XXX (Official Controls Regulation).

8. The control bodies shall transmit to the competent authorities

(a) by 31 January of each year, a list of the operators which were subject to their controls on 31 December of the previous year;

(b) by 31 March ~~of~~ each year, information on the official controls and other official activities carried out in the previous year to support the preparation of the part on organic production and labelling of organic products of the annual report referred to in Article ~~112~~ 113 of the Regulation (EU) XX/XXX (Official Controls Regulation).

19. The Commission shall be empowered to adopt delegated acts in accordance with Article 36 supplementing rules for the performance of official controls and other official activities to verify compliance with the rules laid down by this Regulation. Those delegated acts shall lay down rules on

(a) additional conditions for the delegation of official controls tasks and other official activities to control bodies to those laid down in paragraph 1;

(b) official control tasks and other official activities that shall not be delegated in addition to those laid down in paragraph 3.†

Article 26ca

Actions in case of suspicion + common catalogues (title to be finalised)

1. Where a competent authority, or where appropriate a control authority or control body suspects or receives substantiated information, including from other competent authorities or where appropriate from control authorities or control bodies, that an operator intends to use or to place on the market a product that may not be in compliance with the requirements of this Regulation but bearing terms referring to the organic production, or is informed by an operator in accordance with Article XX:

(a) it shall immediately carry out an official investigation in accordance with Regulation (EU) No XXX/XXX (Official controls Regulation) to be completed as soon as possible, within a reasonable period of time, taking into account the durability of the product and the complexity of the case with a view to verify compliance with the requirements of this Regulation;

(b) it shall provisionally prohibit the placing on the market of the products concerned as organic or in-conversion products and their use in organic production while expecting the results of the investigation referred to in paragraph 1(a). Before taking such a decision, the competent authority, or where appropriate, the control authority, or control body shall allow the operator to comment.

2. In case the results of the investigation referred to in paragraph 1(a) do not show any non-compliance affecting the integrity of organic or in-conversion products, the operator shall be allowed to use the products concerned or to place them on the market as organic or in-conversion products.

3. Member States shall take whatever measures and sanctions are required to prevent fraudulent use of the indications referred to in Chapter IV of this Regulation.

4. Competent authorities shall provide a common catalogue of measures for cases of suspicion of non-compliance and established non compliance to be applied in their territory including by control authorities and control bodies.

5. The Commission may adopt implementing acts to specify uniform modalities for the cases where competent authorities are to take measures in relation to suspicion of non-compliance or to established non-compliance.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 26d

Additional rules on measures in case of non-compliance

1. In the event of non-compliance ~~that~~ affecting ~~ings~~ the integrity of organic or in-conversion products throughout any of the stages of production, preparation and distribution, such as due to ~~the use detection~~ of non-authorized ~~[~~products and~~]~~ substances and ~~]~~ techniques or commingling with non-organic products, competent authorities and, as appropriate, control authorities and control bodies shall ensure, in addition to the measures to be taken in accordance with Article ~~135~~ 138 of the Regulation (EU) No XX/XXXX (Official Controls Regulation) that no reference is made to organic production in the labelling and advertising of the entire lot or production run concerned.

2. In the event of serious, or repetitive or continued non-compliance, competent authorities and/or as appropriate, control authorities and/or control bodies shall ensure that the operators or the group of operators concerned, in addition to the measures referred to in paragraph 1 and any appropriate measures taken in particular in accordance with Article ~~135~~ 138 of the Regulation (EU) No XX/XXX (Official Controls Regulation), are prohibited from marketing products which refer to organic production for a given period, and that their organic certificate be suspended or withdrawn as appropriate.

Article 26e

Additional rules on the exchange of information

1. In addition to the obligations laid down in Article ~~104(1)~~ 105(1) and Article 106(1) of the Regulation (EU) XX/XXXX (Official Controls Regulation), competent authorities, ~~control authorities and control bodies~~ shall immediately share information with other competent authorities, ~~control authorities and control bodies~~ as well as with the Commission on any ~~established or likely~~ suspicion of non-compliance affecting the integrity of organic ~~production or in-conversion products.~~

Competent authorities shall share information with other competent authorities and the Commission via a computer system enabling electronic exchanges of documents and information made available by the Commission.

~~2. In addition to the obligations laid down in Article 31 of Regulation (EU) XX/XXXX (Official Controls Regulation), control bodies to whom competent authorities delegated specific official control tasks or other official activities, shall immediately inform those authorities if the results of the controls carried out on operators or group of operators show established or likely non-compliance affecting the integrity of organic production.~~

~~3. Upon a request duly justified by the need to guarantee that a product has been produced in accordance with this Regulation, competent authorities, control authorities and control bodies shall exchange information on the results of their controls with other competent authorities, control authorities and control bodies as well as with the Commission.~~

2. In case of suspicion of non-compliance or established non-compliance identified with regard to products under the control of other control authorities or control bodies, authorities and control bodies shall immediately inform those other control authorities or control bodies.

2a. Control authorities and control bodies shall exchange other relevant information with other control authorities and control bodies.

~~2b. Upon a request duly justified by the need to guarantee that a product has been produced in accordance with this Regulation, control authorities and control bodies shall exchange information on the results of their controls with other competent authorities, as well as with the Commission.~~

3. Competent authorities shall exchange information on the supervision of the control bodies with the national accreditation bodies as referred to in Article 2(1) of Regulation (EC) No 765/2008.

3a. Competent authorities shall take appropriate measures and establish documented procedures in order to ensure that information on the results of controls is communicated to the paying agency in accordance with the needs of that paying agency as provided for in Article XXX of Regulation 640/2014 (Regulation repealing Regulation 65/2011).

4. The Commission may adopt implementing acts specifying the information to be provided by the competent authorities, the control authorities and control bodies in charge of the official controls and other official activities in accordance with this Article, the relevant recipients of this information, the means by which this information shall be provided, including the modalities of the computer system referred to in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).³⁶

³⁶ Articles 26f and 26g

Chapter VI

Trade with third countries

Article 27

Export of organic products

1. A product may be exported from the Union as organic and bear the organic production logo of the European Union if it complies with this Regulation.

[...]

3. In order to ensure fair competition among operators, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning documents intended for customs authorities in third countries, in particular as regards an organic export certificate issued in electronic form wherever possible and providing assurance that exported organic products comply with this Regulation.

Article 28

Import of organic products

1. A product may be imported from a third country in order to be placed on the market within the Union as organic **or as in-conversion plant reproductive material product or in-conversion food or feed product of plant origin** ~~*as a plant product in conversion/ as in-conversion feed product of plant origin*~~ if the following conditions are met:

(a) the product is a[...] product as referred to in Article 2(1);

(b) the product:

(i) complies with Chapters II, III and IV and all operators, **and groups of operators as referred to in Article 26** including the exporters in the third country concerned, have been subject to the control of control authorities or control bodies recognised in accordance with Article 29 **and are provided by these authorities or bodies with a certificate confirming that all operators or groups of operators are in compliance with this Regulation;**

or

(ii) comes from a third country which is recognised in accordance with [...] article 31 **and complies with the equivalent production and control rules of that third country and is imported with a certificate of inspection issued by the competent authorities, control authorities or control bodies of that third country confirming this compliance;**

or

(iia) **comes from a third country which is recognised in accordance with Article 30 and complies with the conditions laid down in the relevant trade agreement;**

(c) the operators in third countries are able to provide at any time, to the importers [...] **and the national authorities in the Union and in the third countries, information [...] enabling the identification of the operators [...] that are their suppliers and control authorities or control bodies of those suppliers,** with a view to ensuring the traceability of the organic product concerned. **That information shall also be made available also to the control bodies or the control authorities of the importers.**

The Commission may in accordance with ~~the procedures set out in~~ Article 19(5) grant specific authorisations for the use of products and substances in third countries and Outermost regions of the Union, taking into account differences in the ecological balance in plant or animal production, specific climatic conditions, ~~traditions~~ and local conditions in these areas. Such specific authorisations may be granted for a renewable period of ~~two years~~ ~~five years~~ and shall be subject to the principles laid down in Chapter II and to the criteria of Article 19(2) and (3).

When providing for the criteria to qualify as catastrophic circumstances and laying down specific rules on how to deal with them in accordance with Article 17, the Commission shall also take into account differences in the ecological balance, climate and local conditions in third countries and Outermost regions of the Union;}

2. [...] The traceability of imported products intended to be placed on the market within the Union as organic **and their compliance with this Regulation have to be ensured.** The Commission shall by way of [...] **implementing acts lay down specific rules concerning the content of the certificates referred to in paragraph 1, and the procedure to be followed for their issuance, and verification and the technical means by which the certificate is issued, in particular as regards the role of competent authorities, control authorities and control bodies.**

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37 (2).

{3. The respect of the conditions and measures for the import of organic and in-conversion products into the Union shall be ascertained at border control posts, in accordance with Article ~~47(1)~~ 45(4) of Regulation (EU) No XXX/XXX (Official controls regulation). {The physical checks referred to in Article ~~49(2)~~ 47(3) of that Regulation shall be performed at a frequency dependent on the likelihood risk of non-compliance with this Regulation.}

Recognition of control authorities and control bodies

1. The Commission may adopt implementing acts recognising, or withdrawing the recognition of control authorities and control bodies [...] competent to carry out controls **and to issue an organic certificate** in third countries, and establishing a list of those control authorities and control bodies. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

1a. The control authorities or control bodies shall be recognised for the import of the categories of products as listed in Article 25 (5a).

1b. In order to be recognised, the control authorities and control bodies shall fulfil the following criteria:

(a) control authorities and control bodies shall be legally established in one Member State or third country;

(b) control authorities and control bodies shall have the capacity to carry out controls to ensure that the conditions set out in Article 28(1)(a), (b)(i) and (c) and in this Article are met for organic products intended for import into the Union;

(c) control authorities and control bodies shall offer adequate guarantees of objectivity and impartiality and be free from any conflict of interest as regards the exercise of control tasks;

(d) control bodies shall be accredited to the relevant harmonised standard for ‘Conformity assessment – Requirements for bodies certifying products, processes and services’, the reference of which has been published in the Official Journal of the European Union;

(e) control authorities and control bodies shall have the expertise, equipment and infrastructure required to carry out control tasks and a sufficient number of suitable qualified and experienced staff;

(f) additional criteria that may be laid down in a delegated act, adopted pursuant to paragraph 7.

[...]

3. The accreditation referred to in paragraph **1b(d)** may only be granted by:
- (a) a national accreditation body in the Union in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council³⁷; or
 - (b) an accreditation body outside the Union that is a signatory of a multilateral recognition arrangement under the auspices of the International Accreditation Forum.

4. **Control authorities and control bodies shall submit to the Commission a request for recognition consisting of a technical dossier containing all the information needed to ensure that the criteria set out in paragraph 1b are met.**

The [...] control bodies or control authorities shall provide the **accreditation** certificate issued by the accreditation body or respectively the **latest** assessment report issued by the competent authority, and, as appropriate, **latest** reports on the regular on-the-spot evaluation, surveillance and multiannual re-assessment of their activities.

5. Based on the information referred to under paragraph 4 **and on any other relevant information related to the control authority or control body**, the Commission shall ensure appropriate supervision of the recognised control authorities and control bodies by regularly reviewing their **performance and** recognition. For the purposes of that supervision, the Commission may request additional information from the accreditation bodies or, as appropriate, the competent authorities.

6. The nature of the supervision shall be determined on the basis of an assessment of the [...] **likelihood** of non-compliance **taking into account in particular the activity of the control authority or control body, the type of products and operators under its control and the changes in the production standard and control measures.**

³⁷ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

The recognition of control authorities or of control bodies referred to in paragraph 1 shall in particular be withdrawn without delay in accordance with the procedure referred to in paragraph 1 when serious or repetitive infringements as regards the certification or the controls and actions laid down in accordance with paragraph 7b 8 have been detected and when the control body or control authority concerned fails to take appropriate and timely remedial action after request of the Commission within a period which the Commission shall determine according to the severity of the problem and which generally may not be less than 30 days.

~~7.— In order to ensure the transparency of the recognition and supervision procedures, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 [...] supplementing the criteria laid down in paragraph 1b to be applied to the recognition, or the withdrawal of the recognition, of the control authorities and control bodies referred to in paragraph 1, as well as laying down provisions concerning the exercise of the supervision by the Commission, including through on the spot examination.~~

~~***7. The Commission is empowered to adopt delegated acts in accordance with Article 36 amending this Regulation by(i) adding further criteria to those laid down in paragraph 1b to be applied to the recognition, or the withdrawal of the recognition, of the control authorities and control bodies referred to in paragraph 1, or [by] amending those added criteria³⁸.***~~

~~***(ii) deleting or modifying the criteria added pursuant to point (i) of this paragraph.***~~

~~***7a. The Commission is empowered to adopt delegated acts in accordance with Article 36 supplementing this Regulation as regards the exercise of the supervision of the control authorities and control bodies recognised by the Commission in accordance with paragraph 1, including through on-the-spot examination, and as regards the controls and other actions to be performed by those control authorities and control bodies.***~~

³⁸ Similar wording is to be applied during the legal-linguistic revision to remaining empowerments where the Commission is empowered to « amend by adding ».

7b. In order to ensure the effectiveness, efficiency and transparency of the controls of imported products, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning the controls and other actions to be performed by control authorities and control bodies recognised by the Commission for the purpose of this Article.

8. The Commission may adopt implementing acts to ensure the application of measures in relation to cases of non-compliance affecting the integrity of organic products imported under the recognition provided for in this Article or suspicion of such cases. Such measures may consist in particular in the verification of the integrity of the organic products before placing the products on the market within the Union and, where appropriate, the suspension of the authorisation of placing on the market within the Union of such products as organic. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

9. On duly justified imperative grounds of urgency relating to the protection against unfair practices or practices which are incompatible with the principles and rules on organic production, the protection of consumers' confidence or the protection of fair competition between operators, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 37(3) to take the measures referred to in paragraph 8 of this Article or to decide on the withdrawal of the recognition of the control authorities and control bodies referred to in paragraph 1 of this Article.

Article 30

Equivalence under a trade agreement

A recognised third country referred to in [...] Article 28(1)(b)(**ia**) is a third country which the Union has recognised under a trade agreement as having a system of production meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity as those of the Union.

~~{The Commission shall publish, and shall provide the European Parliament and the Council with, regular status reports on all ongoing negotiations on such trade agreements and a list of differences between the production rules and the control measures in the third country involved compared to the rules and measures that are applied within the Union. The final results of the negotiations shall be presented to the European Parliament and the Council, and shall be published, listing in detail any differences between the production rules and control measures applied in the third country concerned and those applied in the Union.~~

~~The Commission shall present a proposal on how to deal with the differences between the third country in question and the European Union when it comes to the production rules and the control measures.~~

~~The Commission shall publish a list of the differences between the production and control provisions contained in all existing trade agreements covered by this Article.]~~

Article 31

Equivalence under Regulation (EC) No 834/2007

1. A recognised third country referred to in [...] Article **28(1)(b)(ii)** is a third country which has been recognised for the purposes of equivalence under Article 33(2) of Regulation (EC) No 834/2007, including those recognised under the transitional measure provided for in Article [...] **42**.

The recognition of the third countries referred to in the first subparagraph shall expire on [*a date to be inserted which corresponds to 5 years following the date of application of the Regulation*].

2. On the basis of annual reports to be sent to the Commission, by 31 March of each year, by the third countries referred to in paragraph 1 regarding the implementation and enforcement of the control measures established by them, **and in the light of any other information received**, the Commission; ~~if requested, assisted by the Member States~~ shall ensure appropriate supervision of the recognised third countries by regularly reviewing their recognition. **For this purpose, the Commission may request the assistance of Member States.** The nature of the supervision shall be determined on the basis of an assessment of the [...] **likelihood** of non-compliance, **taking into account in particular the volume of exports to the Union from the third country concerned, the results of the monitoring and supervisory activities carried out by the competent authority and the results of previous controls. The Commission shall regularly report to the European Parliament and the Council on the outcome of its review.**

[...]

4. The Commission shall, by means of an implementing act, establish a list of the third countries referred to in paragraph 1 and may amend that list by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

5. In order to ensure the management of the list of third countries referred to in paragraph 4, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning the information to be sent by those third countries necessary for the supervision of their recognition by the Commission, as well as the exercise of that supervision by the Commission, including through on-the-spot examination.

6. The Commission may adopt implementing acts to ensure the application of measures in relation to cases of non-compliance affecting the integrity of organic products imported from third countries referred to in this Article or suspicion of such cases. Such measures may consist in particular in the verification of the integrity of the organic products before placing the products on the market within the Union and, where appropriate, the suspension of the authorisation of placing on the market within the Union of such products as organic.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

Article 31a

Report from the Commission on the application of Articles 30 and 31

By December 2020 the Commission shall present a report to the European Parliament and the Council on the state of play concerning the application of Article 30 and 31, in particular as regards the recognition of third countries for the purpose of equivalence.

Chapter VII

General provisions

SECTION 1

FREE MOVEMENT OF ORGANIC PRODUCTS

Article 32

Non-prohibition and non-restriction of the marketing of organic products

1. Competent authorities, control authorities and control bodies may not, on grounds relating to the production, to the labelling or to the presentation of the products, prohibit or restrict the marketing of organic products controlled by another competent authority, control authority or control body located in another Member State, if those products comply with this Regulation. In particular, no official controls and other official activities other than those under Regulation (EU) No XXX/XXX (Official controls Regulation) may be performed and no fees for official controls and other official activities other than those provided for in Chapter VI ~~under Article 76~~ of that Regulation may be collected.

[...]

SECTION 2

INFORMATION AND REPORTING

Article 33

~~Information relating to the organic sector and trade~~³⁹

~~1. Each year Member States shall transmit to the Commission the information necessary for the implementation and monitoring of the application of this Regulation. As far as possible, such information shall be based on established sources of data. The Commission shall take into account the data needs and synergies between potential data sources, in particular their use for statistical purposes when appropriate.~~

~~2. The Commission shall adopt implementing acts as regards the system to be used for transmitting the information referred to in paragraph 1, the details of information to be transmitted, and the date by which that information is to be transmitted.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).~~

Article 34

Information relating to the competent authorities, control authorities and control bodies

1. Member States shall keep a regularly updated list containing:

³⁹ — A list T18

(a) the names and addresses of the competent authorities;

(b) the names and addresses of the control authorities and control bodies, and their code numbers.

~~Insofar as this is not already required under Article 4(4) of Regulation XX/XXXX (Official Controls), Member States shall transmit make public these lists, and any change thereof, to the Commission referred to in point (b) of the first subparagraph and make them public.~~

~~2. Based on the information provided for under paragraph 1, the Commission shall regularly publish annually on the internet an updated the list of control authorities and control bodies referred to in point (b) of paragraph 1.~~

Article 35

End of Derogations, authorisations and report

1. The derogations to the use of organic plant reproductive material, ~~aquaculture juveniles~~ and animals ~~livestock~~, provided under points 1.4.2.1 of part I of Annex II, ~~4.1.2.1(db) of Part III of Annex III~~ and 1.3.5b and 1.3.5c.4 of part II of Annex II ~~with the exception of point 1.3.5.2 of Part II of Annex II,~~ shall end on ~~1 January 2030 at the latest~~ 15 years after the date of application.

~~However, as of 2027 7 years after the date of application,~~ based on the conclusions as regards availability of ~~organic plant reproductive material and animals and organic protein feed for poultry and porcine animals presented and in case the report provided for under paragraph 3 shows a sufficient availability on the Union market of organic plant reproductive material, aquaculture juveniles and animals, covered by the derogation referred to in 1.3.5.b, 1.3.5c,~~ the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending this Regulation by :

- ending at an earlier date or extending these derogations ~~referred to in points in point 1.4.2. of part I of Annex II and in 1.3.5.b and 1.3.5c of Annex II, Part II beyond 15 years after the date of application or at an earlier date.~~

~~ending the derogation referred to in point 1.3.5.2 of Part II of Annex II,~~

~~- ending at an earlier date or extending beyond 5 years after the date of application, the authorisations to use non-organic protein feed in the nutrition of poultry and porcine animals referred to in points 1.8.3.1 (c) and 1.8.4.2 (c) of Part II of Annex II.]-at an earlier date.~~

~~When extending the derogations or authorisations referred to in this paragraph, the Commission shall do so only for as long as it has information, in particular provided by Member States in accordance with paragraph 2, that confirms the unavailability on the market.~~

~~As of 5 years after the date of application, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 amending Article 19a paragraph 2 (b) to extend the scope of the information system referred to in Article 19a (2) to pullets and point 1.3.5b Annex II, part II to base the derogations concerning pullets on the data collected in accordance with this system.~~

~~2. — By the 30th of June of each year, Member States shall transmit to the Commission and to the other Member States information on the derogations referred to in paragraph 1 granted on their territory during the previous calendar year.~~

~~2. By 30th June of each year, Member States shall make available to the Commission and to the other Member States information provided in the database, as referred to in Article 19a, paragraph 1 and in the systems referred to in paragraph 2 and, if relevant, in the systems referred to in [Article 19a], paragraph 3, as well as about information relating to the derogations granted in accordance with point 1.4.2 of Part I of Annex II and point 1.3.5/a, 1.3.5b and 1.3.5c of Part II of Annex II and information on the availability on the market of the Union of organic protein feed for poultry and porcine animals and on the authorisations granted in accordance with points 1.8.3.1 (c) and 1.8.4.2 (c) of Part II of Annex II.~~

~~3. By 31 December /2025 5 years after the date of application, the Commission shall present a report to the European Parliament and the Council on the availability on the Union market of and, if relevant on the causes of limited access to:~~

~~- organic plant reproductive material~~

~~- organic animals covered by the derogations referred to in point 1.3.5/a, 1.3.5b and 1.3.5c of part II of Annex II~~

- organic protein feed intended for the nutrition of poultry and porcine animals and the authorisations referred to in points 1.8.3.1 (c) and 1.8.4.2 (c) of Part II of Annex II.

~~organic aquaculture juveniles.~~

In drawing up this report, the Commission shall take into account in particular the data collected in accordance with Article 19a and the information related to the derogations and the authorisations referred to in paragraph 2.

~~4. By 31 December [2025 5 years after the date of application], the Commission shall present a report to the European Parliament and the Council on:~~

~~the use of organic plant reproductive material [, and the availability and use of other plant reproductive material suitable for organic production], in relation to climate, soil, altitude and geography conditions;~~

~~the situation of organic pig farming and poultry farming, including stocking density criteria, feeding, health care, animal welfare, and disease management;~~

~~the availability of the other breeds and strains suitable for organic production.~~

~~the availability of young poultry, parent animals for poultry production and slow growing poultry strains;]~~

Chapter VIII

Procedural, transitional and final provisions

SECTION 1

PROCEDURAL PROVISIONS

Article 36

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

1a. The delegation of power referred to in Articles [.....] shall be conferred on the Commission for a period of 5 years from the date of application of this Regulation. The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

2. The delegation of power referred to in [.....] may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

2a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement on Better Law making of 13 April 2016.

3. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

4. A delegated act adopted pursuant to [...] shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 37

Committee procedure

1. The Commission shall be assisted by a Committee called the ‘Organic production Committee’. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

~~3a.~~ In the case of implementing acts referred to in this Regulation where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.~~†~~

SECTION 2

REPEAL, AMENDMENTS, TRANSITIONAL AND FINAL PROVISIONS

Article 38

Repeal

Regulation (EC) No 834/2007 is repealed.

However, Regulation (EC) No 834/2007 shall continue to apply for the purposes of completing the examination of pending applications from third countries, as provided for in Article 42 of this Regulation.

Article 39

[...]

[Article 40]

[...]

Article 41

Transitional measures relating to control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007

1. The recognition of control authorities and control bodies granted under Article 33(3) of Regulation (EC) No 834/2007 shall expire ~~on~~ **by up to a maximum of three years ~~one year~~ after the date of application of this Regulation** ~~31 December 2019⁴⁰~~ **at the latest.**

⁴⁰ ~~— A list T18~~

2. The Commission shall, by means of an implementing act, establish a list of the control authorities and control bodies recognised under Article 33(3) of Regulation (EC) No 834/2007 and may amend that list by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 37(2).

3. In order to ensure the management of the list of control authorities and control bodies referred to in paragraph 2, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning the information to be sent by those control authorities and control bodies necessary for the supervision of their recognition by the Commission, as well as the exercise of that supervision by the Commission, including through on-the-spot examination.

Article 42

Transitional measures relating to applications from third countries submitted under Article 33(2) of Regulation (EC) No 834/2007

1. The Commission shall complete the examination of applications from third countries submitted under Article 33(2) of Regulation (EC) No 834/2007 which are pending at the date of entry into force of this Regulation. Regulation (EC) No 834/2007 shall apply to the examination of such applications.

2. In order to facilitate the completion of the examination of the applications referred to in paragraph 1, the Commission shall be empowered to adopt delegated acts in accordance with Article 36 concerning the procedural rules necessary for the examination, including on the information to be submitted by the third countries.

Article 43

~~Transitional measures for stocks of organic products produced in accordance with Regulation (EC) No 834/2007⁴¹~~

~~Products produced in accordance with Regulation (EC) No 834/2007 and placed on the market before 1 July January 2018⁷ [date of application of this Regulation] may continue to be placed on the market marketed after that date until stocks are exhausted.⁴²~~

~~Article 44~~

[...]

~~Article 45~~⁴³

Entry into force and application

This Regulation shall enter into force on the third day following that of its publication in the Official Journal of the European Union.

It shall apply from 1 July 2020 2017⁴⁴.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament

For the Council

The President

The President]

⁴¹ — A list T18

⁴² — A list T18

⁴³ — A list T18

⁴⁴ — At least 6 months after enter into force.

OTHER PRODUCTS REFERRED TO IN ARTICLE 2(1)

- yeasts used as food or feed;
 - **maté, sweetcorn, vine leaves, palm hearts, hop shoots, and other similar edible parts of plants and products produced therefrom;**
 - [...]
 - sea salt **and other salts for food and feed;**
 - **silkworm cocoon suitable for reeling;**
 - natural gums and resins;
 - beeswax;
 - essential oils;
 - **cork stoppers of natural cork, not agglomerated and without any binding substances;**
 - [...]
 - **cotton, not carded or combed;**
 - **wool, not carded or combed;**
 - **raw hides and untreated skins;**
 - **plant-based traditional herbal preparations.**
-

Specific Detailed production rules referred to in chapter III

Part I: Plant production rules

In addition to the production rules laid down in Articles 7 to 10, the rules set out in this Part shall apply to organic plant production.

1. General requirements

~~1.1. Organic crops, *except those which are naturally grown in water*, shall be produced in living soil or in living soil mixed or fertilised with materials and products allowed in organic production in connection with the subsoil and bedrock. in accordance with the principle of soil-related crop cultivation~~

1.1a Hydroponic production, which is a method of growing plants, **which are not naturally growing in water**, with their roots in a nutrient solution only or in an inert medium to which a nutrient solution is added, is prohibited.

1.1b. ~~***By way of derogation from paragraph 1.1,***~~ the production of sprouts by moistening of seeds ~~***and the obtaining of chicory heads including by dipping in clear water,***~~ shall be allowed.

~~***1.1c By way of derogation from paragraph 1.1(new), the following practices shall be allowed:***~~

~~***i) growing plants for the production of ornamentals and herbs in pots to be sold together with the pot to the final consumer;***~~

~~***ii) growing seedlings or transplants in containers for ~~on growing purposes~~ further transplanting.***~~

1.1.d By way of derogation from point 1.1, growing crops in demarcated beds shall only be allowed for the surfaces that have been certified as organic for this practice before 28 June 2017 in Finland, Sweden and Denmark. Any extension of these surfaces shall not be permitted.

This derogation shall end 10 years from the date of application of this Regulation.

Five years after the date of application of this Regulation, the Commission shall present a report to the European Parliament and the Council on the use of demarcated beds in organic agriculture. This report may be accompanied, if appropriate, by a legislative proposal as regards the use of demarcated beds in organic farming.

1.2. All plant production techniques used shall prevent or minimise any contribution to the contamination of the environment.

1.3. Conversion

1.3.1. For plants and plant products to be considered organic, the production rules laid down in this Regulation 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 **organic** feed [...], or, in the case of perennial crops other than forage, at least three years before the first harvest of organic products.

In case of simultaneous conversion of a production unit that includes livestock and land used for growing perennial crops for animal feed not used as forage, the conversion period provided for in the first subparagraph may be reduced to two years, if the animals are mainly fed with products from the production unit in accordance with point 1.4.3.1 of Part II of Annex II or with organic feed.

1.3.2 The competent authority may decide, in the cases where the land **for one or more parcels** has **have** been contaminated with products not authorised for organic production, to extend the conversion period **for the land or parcels concerned** beyond the period referred to in point 1.3.1.

1.3.3 In the case of treatment with a product not authorised for organic production, the competent authority shall require a new conversion period in accordance with point 1.3.1.

That period may be shortened in the following two cases:

- (a) treatment with a product not authorised for organic production as part of a compulsory control measure for pests or weeds, including quarantine organisms or invasive species, imposed by the competent authority of the Member State;

(b) treatment with a product not authorised for organic production as part of scientific tests approved by the competent authority of the Member State.

1.3.4 In the cases referred to in points 1.3.2. and 1.3.3., the length of the conversion period shall be fixed taking into account the following factors:

- (a) the process of degradation of the product concerned shall guarantee, at the end of the conversion period, an insignificant level of residues in the soil and, in the case of a perennial crop, in the plant;
- (b) the harvest following the treatment may not be sold [...] as organic **or as in-conversion products**.

1.3.4.(1)(a) Member States shall inform the Commission and the other Member States of any decision taken by them which lays down compulsory measures related to treatment with a product non-authorised for organic production;

1.3.4.(1)(b) In the case of treatments with a product which is not authorised for organic production, the provisions of point 1.3.5.2 shall not apply.

1.3.5 The specific conversion rules for land associated with organic livestock production should be as follows:

1.3.5.1 The conversion rules shall apply to the whole area of the production unit on which animal feed is produced.

1.3.5.2 Notwithstanding point 1.3.5.1., the conversion period may be reduced to one year for pasturages and open air areas used by non-herbivore species.

1.4 Origin of plants including plant reproductive material

1.4.1 For the production of plants and plant products **other than plant reproductive material**, only organically produced ~~organically produced~~ **[organic⁴⁵]** plant reproductive material shall be used.

⁴⁵ — A list T18

1.4.1a ~~¶~~**To obtain organic plant reproductive material**⁴⁶~~¶~~ this end, the plant intended for plant reproductive material production and, where relevant, the mother plant shall have been produced in accordance with [...] ~~¶~~**this Regulation**⁴⁷~~¶~~ ~~the requirements applicable to organic production units~~ for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.

~~¶~~**Notwithstanding Regulation 2100/94 on Community plant variety rights, operators may, in order to foster local adaptation of plants, use the plant reproductive material obtained from the multiplication of cultivated plants on their own farm.**~~¶~~

~~¶~~**1.4.1a. Organic varieties, which are bred to meet the specific needs and objectives of organic agriculture shall be used in priority. That priority shall not be detrimental to the use of heterogeneous material.**~~¶~~

~~¶~~**1.4.1aa. When choosing organic plant reproductive material operators shall give preference to organic plant reproductive material suitable for organic agriculture.**~~¶~~

1.4.1b. For the production of organic varieties, the organic breeding activities shall be conducted under organic conditions and focus on enhancement of genetic diversity, reliance on natural reproductive ability, as well as agronomic performance, disease resistance and adaptation to diverse local soil and climate conditions.

All multiplication practices except meristem culture shall be under certified organic management.

~~¶~~1.4.2. Use of **non-organic** plant reproductive material ~~not obtained from organic production~~⁴⁸~~¶~~
~~[units]~~

[...]

⁴⁶ — A list T18

⁴⁷ — A list T18

⁴⁸ — A list T18

~~1.4.2.1~~ By way of derogation from point 1.4.1, where the data collected in the seeds database referred to in Article 19a(1) or the system referred to in Article 19a(2)(a) shows that the qualitative or quantitative needs of the farmer regarding relevant organic plant reproductive material, excluding seedlings, are not met, competent authorities may authorise the use of in-conversion or non-organic plant reproductive material under the conditions laid down under points 1.4.2.24 to 1.4.2.5. ~~and 1.4.3.~~

Prior to requesting any such derogation the farmer shall consult the seeds database as referred to ~~laid out~~ in point 1 of Article 19a or the system referred to in point ~~or~~ (2)(a) of Article 19a in order to verify whether his or her request is justified.

~~1.4.2.1~~ For operators in third countries, control authorities or control bodies recognised in accordance with Article 29(1) may authorise the use of in-conversion or non-organic plant reproductive material onto an organic production unit, when organic plant reproductive material is not available in sufficient quality or quantity in the territory of the country where the operator is located and under the conditions laid down under points 1.4.2.2 to 1.4.2.5.

1.4.2.2 non-organic plant reproductive material shall not be treated with plant protection products, other than those authorised for treatment of seed in accordance with Article 19(1) of this Regulation, unless chemical treatment is prescribed in accordance with Regulation (EU) No XX/XXX of the European Parliament and of the Council (protective measures against pests of plants) for phytosanitary purposes by the competent authority of the Member State for all varieties of a given species in the area where the plant reproductive material is to be used.

~~1.4.2.3~~ Member States may confer the responsibility for granting authorisation(s) referred to in points 1.4.2.1 to control authorities or delegate it to another public administration under their supervision or to control bodies.⁴⁹

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

⁴⁹ — A list T18

~~1.4.2.5~~ The authorisation shall be granted only to individual users for one season at a time and the competent authority ~~or body~~ responsible for the authorisations shall list the quantities of plant reproductive material authorised. ⁵⁰

~~1.4.3. Priority use of organic varieties~~

~~Notwithstanding rules on the organic status of plant reproductive material, organic varieties shall be primarily used in organic production units when a minimum of [10] organic varieties per species has been reached or are available in sufficient quantities, according to the national database referred to in point (a) of paragraph (1) of Article [19a].~~

~~That priority shall not be detrimental to the use of heterogeneous material.]~~

1.5 Soil management and fertilisation

1.5.1 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.

1.5.2. The fertility and biological activity of the soil shall be maintained and increased [...]:

- (i) except in the case of grassland or perennial forage, by multiannual crop rotation including mandatory [...] leguminous crops as the main or cover crop for rotating crops and other green manure crops, and
- (ii) in the case of greenhouses or perennial crops other than forage, by short term green manure crops and legumes as well as the use of plant diversity and
- (iii) in all cases by the application of livestock manure or organic [...] matter, both preferably composted, from organic production.

⁵⁰ — A list T18

1.5.3. Where the nutritional needs of plants cannot be met by measures provided for in points 1.5.1. and 1.5.2. only fertilisers and soil conditioners authorised for use in organic production pursuant to Article 19 may be used and only to the extent necessary. **Operators shall keep records of the use of these products.**

~~1.5.4~~ The total amount of livestock manure, as defined in Council Directive 91/676/EEC, applied ***on the in-conversion and organic production units*** agricultural holding, shall not exceed 170 kg of nitrogen per year/hectare of agricultural area used. That 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.⁵⁴

1.5.5. [...] Agricultural holdings may establish written cooperation agreements exclusively with other agricultural holdings and enterprises which comply with the organic production rules, with the intention of spreading surplus manure from organic production **units**. The maximum limit as referred to in point 1.5.4., shall be calculated on the basis of all of the organic production units involved in such cooperation.

1.5.6. 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.

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

1.5.8 Mineral nitrogen fertilisers shall not be used.

1.5.8a. Biodynamic preparations may be used.

~~1.5.8b. The use of ferti-irrigation is prohibited.~~

1.6 Pest and weed management

⁵⁴ — A list T18

1.6.1 The prevention of damage caused by pests and weeds shall rely primarily on the protection by:

- natural enemies,
- the choice of species, varieties and heterogeneous material
- crop rotation,
- cultivation techniques such as biofumigation, **mechanical and physical methods**, and
- thermal processes such as solarisation and, **in the case of protected crops**, shallow steam treatment of the soil (to a maximum depth of 10 cm).

1.6.2 Where plants cannot be protected adequately from pests by measures provided for in point 1.6.1. or in the case of an established threat to a crop, only products authorised for use in organic production pursuant to **Articles 7 and 19** may be used and only to the extent necessary. **Operators shall keep documentation proving the need for the use of such products.**

1.6.3. **In relation to products used in [...]** traps or dispensers of products other than pheromones, **the traps and/or dispensers** shall prevent the substances from being released into the environment and **shall** prevent contact between the substances and the crops being cultivated. [...] **All traps including pheromone traps** shall be collected after use and **safely** disposed of [...].

1.7 Products used for cleaning and disinfection

With regard to cleaning and disinfection, only the products for cleaning and disinfection in plant production authorised for use in organic production pursuant to Article 19 shall be used.

1.7a Record keeping obligation

Operators shall keep documentation on the parcels concerned and on the amount of the harvest.

1.8. Preparation of unprocessed products

If preparation operations, other than processing, are carried out on plants, the general requirements laid down in points 1.2., 1.3, 1.4., 1.5 of Part IV shall apply *mutatis mutandis* to such prepared products.⁷

2. [...] Detailed rules for specific ~~and cultivation practices~~ for [...] plants and plant production

2.1 Rules on mushroom production

For the 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 [...] **organic production units or from in-conversion units in their second year of conversion**; or
 - (ii) referred to in point 1.5.3., only when the product referred to in point (i) is not available, provided that these farmyard manure and animal excrements 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 **organic production units** [...];
- (c) peat not chemically treated;
- (d) wood, not treated with chemical products after felling;
- (e) mineral products referred to in point 1.5.3., water and soil.

2.2 Rules concerning the collection of wild plants

The collection of wild plants and parts thereof, growing naturally in natural areas, forests and agricultural areas is considered as organic production 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 pursuant to Articles 7 and 19;
- (b) the collection does not affect the stability of the natural habitat or the maintenance of the species in the collection area.

PART II: Livestock production rules

In addition to the production rules laid down in Articles 7, 8, 9 and 11, the rules laid down in this Part shall apply to livestock production.

1. General requirements

1.1 **Except in the case of beekeeping**, landless livestock production shall be prohibited, where the farmer [...] **intending to produce organic** livestock does not manage agricultural land and has not established a written cooperation agreement with [...] a [...] farmer **as regards the use of organic production units or in-conversion production units for that livestock**.

1.2 Conversion

[...]

~~1.2.1.~~ In the case of simultaneous start of conversion of the complete production unit, including livestock, pasturage or any land used for animal feed, animals and animal products may be considered organic at the end of the conversion period of the complete production unit.

In case non-organic animals are introduced on an in-conversion production unit after the start of the conversion period, these animals and animal products produced by them may be considered organic at the end of the conversion period of the production unit or of the conversion period laid down in point 1.2.2. for the type of animal concerned, whichever is later.⁵²

1.2.2. Conversion periods specific to the type of animal production are set out [...] **as follows:**

- (a) 12 months in the case of bovine and equine animals for meat production, and in any case at least three quarters of their lifetime;**
- (b) six months in the case of ovine, caprine and porcine animals and animals for milk production;**
- (c) 10 weeks for poultry for meat production, except for Peking ducks, brought in before they are three days old;**
- (d) Seven weeks for Peking ducks, brought in before they are three days old;**
- (e) six weeks in the case of poultry for egg production, brought in before they are three days old;**
- (f) 12 months for bees.**

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

However, non-organic beeswax may be used:

- (i) where beeswax from organic beekeeping is not available on the market;**
- (ii) where it is proven free of contamination by products or substances not authorised for organic production; and**
- (iii) provided that it comes from the cap**

⁵² — A list T18

(g) **three months for rabbits.**

(h) **twelve months for cervine animals.**

[...]

~~[1.2.4. Animals and animal products may only be considered organic at the end of the conversion period if there is simultaneous conversion of the complete production unit, including livestock, pasturage or any land used for animal feed.⁵³]~~

1.3 Origin of animals

1.3.1. **Without prejudice to the rules on conversion**, organic livestock shall be born **or hatched** and raised on organic **production units** [...].

~~[1.3.2. Animals existing on the agricultural holding at the beginning of the conversion period and their products may be deemed organic after compliance with the applicable conversion period referred to in point [...] **1.2.2 and the provision in point 1.2.4.**⁵⁴]~~

1.3.3. With regard to the breeding of organic animals:

- (a) reproduction shall use natural methods; however, artificial insemination shall be allowed;
- (b) reproduction shall not be induced **or impeded** by treatment with hormones or other substances with a similar effect, unless as a form of veterinary therapeutic treatment in case of an individual animal;
- (c) other forms of artificial reproduction, such as cloning and embryo transfer, shall not be used;
- (d) the choice of breeds shall be appropriate, [...] shall **ensure a high standard of animal welfare** and shall contribute to the prevention of any suffering and to avoiding the need for the mutilation of animals.

⁵³ — A list T18

⁵⁴ — A list T18

1.3.4 **When choosing** ~~In the choice of breeds or strains,~~ **operators shall consider giving preference to breeds or strains, with a high degree of genetic diversity,** account shall be taken of the capacity of animals to adapt to local conditions, **their breeding value, their longevity,** ~~without impairment of their welfare,~~ their vitality and their resistance to disease **or health problems, all without impairment of their welfare.** In addition, ~~[organic]~~ 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, **possibly leading to** pale-soft-exudative (PSE) **meat** syndrome, sudden death, spontaneous abortion and difficult births requiring caesarean operations. Preference shall be given to indigenous breeds and strains.

~~†To choose the breeds and strains in accordance with the first subparagraph, operators shall use the information available in the systems referred to in paragraph 3 point (b) of paragraph 4 of Article 19a.~~

1.3.5 Use of non-organic animals

By way of derogation from point 1.3.1, for breeding purposes, non-organically raised animals may be brought onto an [organic production unit agricultural holding] when breeds are in danger of being lost to farming in accordance with Article 7(3) of Commission Delegated Regulation (EU) No 807/2014 Annex IV to Commission Regulation (EC) No 1974/2006 and in that case animals of those breeds must not necessarily be nulliparous.

~~†1.3.5a~~ By way of derogation from point 1.3.1, ~~†~~for the renovation of apiaries, 20% 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. In any case, one swarm or queen bee may be replaced per year by a non-organic swarm or a queen bee.

~~1.3.5b~~ *By way of derogation from point 1.3.1, when a flock is constituted for the first time, renewed or reconstituted, ~~where qualitative and quantitative needs of farmers cannot be met, competent authorities may decide that~~ 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. ~~Products derived from them may only be considered as organic provided that the conversion period specified in point 1.2 of Part II of this Annex is respected.~~*

1.3.5.c~~a~~ By way of derogation from points 1.3.1, where the data collected according to the system referred to in Article 19a (2~~1~~) (b) shows that the qualitative or quantitative needs of the farmer regarding organic animals are not met, competent authorities may authorise the introduction of non-organic animals onto an organic production unit, subject to the following conditions provided for in points 1.3.5.1 to 1.3.5.4a.

Prior to requesting any such derogation the farmer shall consult the data collected as laid out in ~~point 1(b) of~~ Article 19a(2)(b) in order to verify whether his or her request is justified.

~~For operators in third countries, control authorities or control bodies recognised in accordance with Article 29(1) may authorise the introduction of non-organic animals onto an organic production unit, when organic animals are not available in sufficient quality or quantity in the territory of the country where the operator is located.~~

1.3.5.4~~1~~ For breeding purposes, non-organic young animals may be introduced when a herd or flock is constituted for the first time. They 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 those animals enter the herd or flock:

- (a) bovine, equine and cervine animals shall be less than six months old;
- (b) ovine and caprine animals shall be less than 60 days old;
- (c) porcine animals shall weigh less than 35 kg.

(d) rabbits shall be less than 3 months old;

1.3.5.1.2 For breeding purposes, non-organic adult male and nulliparous female animals may be introduced for the renewal of a herd or flock. They shall be reared subsequently in accordance with the organic production rules. Moreover, the number of female animals shall be subject to the following restrictions per year:

(a) up to a maximum of 10 % of adult equine or bovine animals; and 20 % of the adult porcine, ovine, caprine animals, rabbits and cervine animals;

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

1.3.5.32. The percentages referred to in sub-point 1.3.5.1.2 may be increased up to 40%, provided that the competent authority has confirmed that the one of following conditions is fulfilled:

(a) a major extension to the farm has been undertaken;

(b) a breed has been changed;

(c) a new livestock specialisation has been initiated;

~~(d) breeds are in danger of being lost to farming as defined by Member States in accordance with Article 7(3) of Commission Delegated Regulation (EU) No 807/2014, and in that case animals of those breeds must not necessarily be nulliparous.~~

~~1.3.5.3 For the renovation of apiaries, 20% 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. In any case, one swarm or queen bee may be replaced per year by a non-organic swarm or a queen bee.~~

~~1.3.5.4 When a flock is constituted for the first time, renewed or reconstituted, 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.]~~

1.3.5.4a In the cases referred to in points 1.3.5.1 to 1.3.5.34, non-organic animals ~~[and products derived from them]~~ may only be considered as organic provided that the conversion period specified in point 1.2 of Part II of this Annex is respected.

1.4 Nutrition

1.4.1 General nutrition requirements

With regard to nutrition the following rules shall apply:

- (a) feed for livestock shall be obtained primarily from the agricultural holding where the animals are kept or from organic **or in-conversion production units of** other holdings in the same region;
- (b) livestock shall be fed with organic **or in-conversion** feed that meets the animal's nutritional requirements at the various stages of its development. Restricted feeding shall not be permitted in livestock production **unless justified for veterinary reasons**;
- (c) the keeping of livestock in conditions, or on a diet which may encourage anaemia, shall be prohibited;
- (d) fattening practices shall [...] **always respect the normal nutrition patterns for each species and animals' welfare** at any stage of the rearing process. Force-feeding is forbidden;
- (e) with the exception of bees, **porcine and poultry**, livestock shall have permanent access to pasture **whenever conditions allow** or to roughage;
- (f) growth promoters and synthetic amino-acids shall not be used;

(g) suckling animals shall be fed in preference on maternal milk for a minimum period **laid down by the Commission in accordance with Article 11; Milk replacers containing chemically synthesised or components of plant origin shall not be used during this period.**

(h) feed materials of [...] **plant, algae, animal or yeast origin shall be organic.**

(ha) **Non-organic feed materials of plant, algae, animal or yeast origin, feed materials of microbial or of mineral origin, feed additives and processing aids may be used only if they have been authorised for use in organic production pursuant to Article 19.**

1.4.1a Grazing

~~With regard to grazing, the following rules shall apply:~~

1.4.1a.1. Grazing on organic land

Without prejudice to point 1.4.1a.2., organic animals shall graze on organic land. However, non-organic animals may use organic pasturage for a limited period of time each year, provided that such animals have been raised in an environmental friendly way supported under Articles 23, 25, 28, 30, 31 and 34 of Regulation (EC) No 1305/2013 and that non-organic animals are not present on the organic land at the same time as organic animals.

1.4.1a.2 Grazing on common land and transhumance

1.4.1a.2.1. Organic animals may [...] **graze** on common land, provided that:

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

(b) any non-organic animals which use the land concerned [...] **that have been raised in an environmental friendly way supported under Articles 23, 25, 28, [...] 30, 31 and 34 of Regulation (EU) No 1305/2013;**

(c) any livestock products from organic animals, whilst using this land, [...] **are** not regarded as [...] organic **products** [...], unless adequate segregation from non-organic animals can be proved.

1.4.1a.2.2 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. **During that period, organic livestock shall be kept separate from other livestock.** The uptake of non-organic feed, in the form of grass and other vegetation on which the animals graze, shall be allowed:

(a) for a maximum of 35 days covering both the outward and return journeys; or

(b) for a maximum of 10% of the total feed ration per year calculated as percentage of the dry matter of feeding stuffs from agricultural origin.

1.4.3 In-conversion feed

1.4.3.1 For [...] agricultural holdings **that produce organic livestock:**

(a) up to [...] **25 %** on average of the feed formula of rations may comprise in-conversion feed [...] from the second year of conversion. [...] **When this in-conversion feed comes from the holding where the livestock is kept, this percentage may be increased to 100%; and**

(b) up to [...] **20 %** of the total average amount of feed 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.

When both types of in-conversion feed referred to in points (a) and (b) are being used for feeding, the total combined percentage of such feed shall not exceed the percentage fixed in point [...] **(a).**

[...]

1.4.3.3 The figures in point 1.4.3.1 [...] shall be calculated annually as a percentage of the dry matter of feed of plant origin.

[...]

1.5 Health care

1.5.1 Disease prevention

1.5.1.1. 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.

1.5.1.2 The use of immunological veterinary medicinal products shall be allowed.

1.5.1.3. The use of chemically synthesised allopathic veterinary medicinal products, **including bolus of synthesised allopathic chemical molecules**, or antibiotics for preventive treatment shall be prohibited.

1.5.1.4 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), shall be prohibited.

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

1.5.1.6 With regard to cleaning and disinfection, only the products for cleaning and disinfection in livestock buildings and installations authorised for use in organic production pursuant to Article 19 shall be used.

1.5.1.7 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. Rodenticides (to be used only in traps), and the products authorised for use in organic production pursuant to **Articles 7** and 19 may be used for the elimination of insects and other pests in buildings and other installations where livestock is kept.

1.5.2 Veterinary treatment

1.5.2.1 Where despite preventive measures to ensure animal health animals become sick or injured they shall be treated immediately.

1.5.2.2 Disease shall be treated immediately to avoid suffering of the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions and under the responsibility of a veterinarian, 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.

1.5.2.3 Feed materials of mineral origin and nutritional additives authorised for use in organic production pursuant to Article 19 and phytotherapeutic and homeopathic products shall be used in preference to chemically-synthesised allopathic veterinary treatment including antibiotics, provided that their therapeutic effect is effective for the species of animal, and the condition for which the treatment is intended.

1.5.2.4. 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 including 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, shall not be sold as organic products, and the livestock shall undergo the conversion periods referred to in points 1.2 [...].

1.5.2.5. The withdrawal period between the last administration of a **chemically synthesised** allopathic veterinary medicinal product **and antibiotics** to an animal under normal conditions of use, and the production of organically produced foodstuffs from such animals, [...] **shall** be twice the withdrawal period [...] referred to in Article 11 of Directive 2001/82/EC [...] **and at least 48** hours.

1.5.2.6 Treatments related to the protection of human and animal health imposed on the basis of Union legislation shall be allowed.

1.6 Housing conditions and husbandry practices

1.6.1 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 ensure the well-being of the animals. The building shall permit plentiful natural ventilation and light to enter.

1.6.2. Housing for livestock shall not be mandatory in areas with appropriate climatic conditions to enable animals to live outdoors. [...] Animals shall have access to shelters or shady areas to protect them from adverse weather conditions.

1.6.3 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, move, lie down easily, turn round, groom themselves, assume all natural postures and make all natural movements such as stretching and wing flapping.

1.6.4 The minimum surfaces for indoor and outdoor areas, and [...] **the technical details relating to housing [...], as laid down by the Commission in accordance with Article 11 (4), shall be respected.**

1.6.5 Open air areas may be partially covered. Verandas shall not be considered as open air areas.

1.6.6 The total stocking density shall not exceed the limit of 170 kg of organic nitrogen per year and hectare of agricultural area.

1.6.7 To determine the appropriate density of livestock referred to in point 1.6.6, the competent authority shall set out the livestock units equivalent to the limit referred to in point 1.6.6., following the figures laid down in each of the specific requirement by animal production.

1.6.7a The use of cages, boxes and flat decks to raise livestock shall not be permitted for any livestock species.

~~1.6.7b housing shall have smooth, but not slippery floors.~~⁵⁵

~~1.6.7c 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.~~⁵⁶

1.6.7d when livestock is treated individually for veterinary reasons, it shall be kept in spaces that have a solid floor and must be provided with straw or appropriate bedding. The animal shall be able to turn around easily and to lie down comfortably at full length.

1.6.7e Organic livestock rearing in a pen on very wet or marshy soil shall not be allowed.

1.7 Animal welfare

1.7.1 All persons involved in keeping animals and in handling animals during transport and slaughter shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals and shall have followed adequate training as required in particular in Council Regulation (EC) 1/2005 and Council Regulation (EC) 1099/2009, to ensure proper application of the rules set out in this Regulation.

1.7.2 Husbandry practices, including stocking densities and housing conditions shall ensure that the developmental, physiological and ethological needs of animals are met.

⁵⁵ — A list T18

⁵⁶ — A list T18

1.7.3 [...] Livestock shall have permanent access to open air areas **allowing the animals to exercise**, preferably pasture, whenever weather **and seasonal 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 Union legislation.

1.7.4 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.

[...]

1.7.6. 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 veterinary reasons. **Isolation of livestock may be authorised, for a limited period of time, only when workers safety is compromised and for animal welfare reasons.** Competent authorities may authorise cattle in [...] **farms with a maximum of 50 animals (~~including~~ excluding young stock)** 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, and at least twice a week access to open air areas when grazing is not possible.

1.7.7 Duration of transport of livestock shall be minimised.

1.7.8. Any suffering, **pain and distress** shall be **avoided and** kept to a minimum during the entire life of the animal, including at the time of slaughter.

1.7.9 [...] Without prejudice to further developments in Union legislation on animal welfare, tail-docking for sheep, beak trimming when undertaken in the first three days of life, ~~and~~ dehorning ~~and removal of antlers~~, ~~including disbudding~~ may be exceptionally allowed only on a case-by-case basis when they improve the health, welfare or hygiene of the livestock or when workers safety is compromised. Disbudding may be allowed only on a case by case basis when it improves the health, welfare or hygiene of the livestock or when workers' safety is compromised. ~~Deer antler removal shall be performed only by a veterinarian and under anaesthesia.~~ ~~Disbudding may be allowed on a case by case basis when they improve the health, welfare or hygiene of the livestock or when workers safety is compromised.~~ These operations shall be authorised by a competent authority and carried out by qualified personnel only when the operator has duly justified and notified the reasons to the competent authority.

1.7.10. Any suffering to the animals shall be reduced to a minimum by applying adequate anaesthesia and/or analgesia and by carrying out [...] **any** operation only at the most appropriate age by qualified personnel.

1.7.11. Physical castration shall be allowed in order to maintain the quality of products and traditional production practices but only under [...] **the conditions set out in 1.7.10.**

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

1.7a Preparation of unprocessed products

If preparation operations, other than processing, are carried out on livestock, the general requirements laid down in points 1.2., 1.3, 1.4., 1.5 of Part IV shall apply mutatis mutandis to such prepared products.

1.8. Additional general rules

1.8.1. For bovine, ovine, caprine and equine animals

1.8.1.1. Nutrition

With regard to nutrition, the following rules shall apply:

(a-1). At least 60% of the feed shall come from the farm itself, or, in case this is not available/feasible be produced in cooperation with other organic or in-conversion production units and feed operators using feed and feed material from the same region. This percentage shall be raised to 70% two years after the date of application of this Regulation.

(a) animals shall have access to pasturage for grazing whenever conditions allow;

(b) notwithstanding point (a), male bovine animals over one year old shall have access to pasturage or an open air area;

(b) In cases where animals 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;

(c) rearing systems shall 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 bovine, ovine and caprine, equine animals, 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 shall be allowed.

1.8.1.2. Housing and husbandry practices

With regard to the housing and husbandry practices conditions, ~~for bovine, ovine, caprine and equine animals~~ the following rules shall apply:

a. housing of bovine, ovine and caprine animals shall have smooth, but not slippery floors.

b. 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 authorised as fertiliser or soil conditioner for use in organic production pursuant to Article 19;

Notwithstanding point (a) of the first subparagraph of Article 3(1) and the second subparagraph of Article 3(1) of Council Directive 2008/119/EC⁵⁷, the housing of calves in individual boxes shall be forbidden after the age of one week, unless for individual animals for a limited period of time, and in so far as this is justified for veterinary reasons.

When a calf is treated individually for veterinary reasons, it shall be kept in spaces that have a solid floor and must be provided with straw bedding. The calf should be able to turn around easily and to lie down comfortably at full length.

1.8.2. For cervine animals

1.8.2.1. Nutrition

With regard to nutrition, the following rules shall apply:

(a-1) At least 60% of the feed shall come from the farm itself or, in case this is not available/feasible be produced in cooperation with other organic or in-conversion production units and feed operators using feed and feed material from the same region. This percentage shall be raised to 70% two years after the date of application of this Regulation.

(a) animals shall have access to pasturage for grazing whenever conditions allow;

⁵⁷ Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves (OJ L 10, 15.1.2009, p. 7).

- (b) in cases where animals 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;
- (c) rearing systems shall be based on maximum use of grazing pasturage according to the availability of pastures in the different periods of the year;
- (d) rearing systems shall 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 cervine animals, shall consist of roughage, fresh or dried fodder, or silage. A reduction to 50% for female cervine animals in milk production for a maximum period of three months in early lactation shall be allowed.
- (e) for cervine animals, natural grazing must be ensured in a pen during the period of vegetation. Pens that cannot provide feed by grazing during the period of vegetation shall not be allowed;
- (f) for cervine animals, feeding shall only be allowed in the event of a shortage of grazing due to poor weather conditions;
- (g) for cervine animals, farmed animals in a pen must be provided with clean and fresh water. If a natural source of water that is easily accessible to animals is not available, watering places must be provided.

1.8.2.2. Housing and husbandry practices

With regard to housing and husbandry practices, the following rules shall apply:

- (a) cervine animals must be provided with hiding places, ~~and~~ shelters and fences that do not harm animals;
- (b) in red deer pens, animals must be able to roll in the mud to ensure skin grooming and body temperature regulation;

[(ba) any housing of cervine animals shall have smooth, but not slippery floors;

(bb) any 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 authorised as fertiliser or soil conditioner for use in organic production pursuant to Article 19;⁵⁸]

(c) for cervine animals, feeding places must be installed in areas protected from the weather and accessible both to animals and to persons attending to them. The soil where feeding places are located must be consolidated, and the feeding apparatus must be equipped with a roof;

(d) for cervine animals, if permanent access to feed cannot be ensured, the feeding places must be designed so that all animals can feed at the same time;

1.8.3. For porcine animals

1.8.3.1. Nutrition

With regard to nutrition, the following rules shall apply:

(a) At least **30%** of the feed shall come from the farm itself or, in case this is not **available/feasible**, be produced in cooperation with other organic [...] **or in-conversion production units and** [...] feed operators **using feed and feed material** from [...] the same region.

(b) ~~for porcine animals~~, roughage, fresh or dried fodder, or silage shall be added to the daily ration.

⁵⁸ — A list T18

(c) Where farmers are unable to obtain protein feed exclusively from organic production for porcine animals and the competent authority has confirmed that organic protein feed is not available in sufficient quantity, non-organic protein feed may be used until ~~2~~ five years after the date of application of this Regulation provided that the following conditions are fulfilled:

- (i) it is not available in organic form;**
- (ii) it is produced or prepared without chemical solvents; and**
- (iii) its use is limited to piglets up to 35kg and specific protein compounds**
- (iv) the maximum percentage authorised per period of 12 months for those animals shall not exceed 5 %. The percentage of the dry matter of feed from agricultural origin shall be calculated.**

1.8.3.2. Housing and husbandry practices

With regard to ~~the housing~~ **and husbandry practices**, ~~conditions~~ the following rules shall apply:

- (a) housing of porcine animals shall have smooth, but not slippery floors. [...]**
- (b) the housing of porcine animals 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 authorised as fertiliser or soil conditioner for use in organic production pursuant to Article 19;**
- (ba) there shall always be a straw bed made of straw or other suitable material large enough to ensure that all pigs in a pen can lie down at the same time in the most space-consuming way;**

(c) sows shall be kept in groups, except in the last stages of pregnancy and during the suckling period, **during which time the sow shall be able to move freely in her pen and shall only be tethered for short times.**

(ca) Without prejudice to any additional requirements for straw, a few days before expected farrowing, sows must be provided with a quantity of straw or other suitable natural material sufficient to enable them to build nests;

(d) exercise areas shall permit dunging and rooting by porcine animals. For the purposes of rooting different substrates can be used.

1.8.4. For poultry

1.8.4.1. Origin of animals

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 **adapted to outdoor rearing** [...].

The Competent authority shall define the criteria of slow-growing strains or draw up a list thereof and provide this information to operators, other Member States and the Commission.

Where slow-growing poultry strains are not used by the farmer the minimum age at slaughter shall be as follows:

- (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.

1.8.4.2. Nutrition

{With regard to nutrition, the following rules shall apply:}

- (a) At least 30% of the feed shall come from the farm itself or, in case this is not **available/feasible**, be produced in cooperation with other organic **or in-conversion production units** and [...] feed operators **using feed and feed material from** [...] the same region.
- (b) ~~For poultry~~, roughage, fresh or dried fodder, or silage shall be added to the daily ration.
- (c) **Where farmers are unable to obtain protein feed exclusively from organic production for poultry species and the competent authority has confirmed that organic protein feed is not available in sufficient quantity, non-organic protein feed may be used until ~~two~~ five years after the date of application of this Regulation, provided that the following conditions are fulfilled:**
 - (i) **it is not available in organic form;**
 - (ii) **it is produced or prepared without chemical solvents; and**
 - (iii) **its use is limited to young poultry and specific protein compounds**
 - (iv) **the maximum percentage authorised per period of 12 months for those animals shall not exceed 5 %. The percentage of the dry matter of feed from agricultural origin shall be calculated.**

1.8.4.3. Animal welfare

Live plucking of poultry shall be prohibited.

1.8.4.4. [...] Housing and husbandry practices

With regard to ~~the housing~~ **and husbandry practices**, ~~conditions~~ the following rules shall apply:

- (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) 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 during a period to be established by the Member States in order to allow vegetation to grow back. These requirements shall not apply where poultry are not reared in batches, are not kept in runs and are free to roam, throughout the day.

[...]

- (d) poultry shall have access to an open air area for at least one third of their life [...].

~~**However,**~~ laying hens and finisher poultry shall have access to an open air area for at least one third of their life, except in the case of temporary restrictions imposed on the basis of Union legislation.

- (e) [~~In particular,~~] continuous daytime open air access shall be provided from as early an age as practically possible, whenever physiological and physical conditions allow, except in the case of temporary restrictions imposed on the basis of Union legislation;

(f) By way of derogation from point 1.6.5, in the case of breeding birds and pullets aged under 18 weeks and when the conditions specified in point 1.7.3 as regards restrictions and obligations related to the protection of human and animal health imposed on the basis of Union legislation are met and prevent breeding birds and pullets aged under 18 weeks from having access to open air areas, verandas shall be considered as open air areas and in such cases shall have a wire mesh barrier to keep other birds out.

- (g) open air areas for poultry shall [...] permit fowl to have easy access to adequate numbers of drinking troughs; [...]

- (h) open air areas for poultry shall be mainly covered with vegetation. [...]
- (i) Under conditions where feed availability from the range area is limited, due for instance to long term snow cover or arid weather conditions, supplementary feeding of roughage must be included as part of poultry diets;
- (j) Where poultry are kept indoors due to restrictions or obligations imposed on the basis of Union legislation, they shall permanently have access to sufficient quantities of roughage and suitable material in order to meet their ethological needs.
- (k) 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; when weather conditions do not permit, they shall have access to water which enables them to dip their head therein so as to clean plumage;
- (l) 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;
- (da) the total usable surface area of poultry ~~buildings-houses~~ for fattening poultry of any production unit shall not exceed 1 600 m²**
- ~~{(db) *the total number of laying hens shall not exceed 12 000 hens in an organic or in-conversion production unit.* }~~ **Not more than 3 000 laying hens shall be allowed in one compartment of a poultry-house. *For young poultry, specific rules shall apply;***

1.8.5. For rabbits

1.8.5.1. Nutrition

With regard to nutrition, the following rules shall apply:

(a-1) At least 70% of the feed shall come from the farm itself, or, in case this is not available/feasible be produced in cooperation with other organic or in-conversion production units and feed operators using feed and feed material from the same region.

(a) rabbits shall have access to pasturage for grazing whenever conditions allow;

(b) rearing systems shall be based on maximum use of grazing pasturage according to the availability of pastures in the different periods of the year;

(c) for rabbits, fibrous food such as straw and/or hay must be provided when grass is not sufficient. Forage shall comprise at least 60% of the diet;

1.8.5.2 Housing and husbandry practices:

With regard to housing and husbandry practices, the following rules shall apply:

(a) 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 authorised as fertiliser or soil conditioner for use in organic production pursuant to Article 19;⁵⁹

(b) rabbits shall be kept in groups.

(c) rabbit farms shall use robust breeds adapted to outdoor conditions;

(d) rabbits shall have access to:

(i) covered shelter including dark hiding places;

⁵⁹ — A list T18

- (ii) **an outdoor run with vegetation, preferably pasture,**
- (iii) **a raised platform on which they can sit, either inside or out;**
- (iv) **nesting material for all nursing does.**

1.8.6. For bees

1.8.6.1. Origin of animals

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

1.8.6.2. Nutrition

With regard to nutrition, the following rules shall apply:

- (a) at the end of the production season hives shall be left with sufficient reserves of honey and pollen to survive the winter;
- (b) the feeding of bee colonies shall only be permitted where the survival of the hives is endangered due to climatic conditions. Feeding shall be with organic honey, organic sugar syrups, or organic sugar.

1.8.6.3. Health care

With regard to health care, the following rules shall apply:

- (a) For the purposes of protecting frames, hives and combs, in particular from pests, only rodenticides (to be used only in traps), and appropriate products authorised for use in organic production pursuant to **Articles 7 and 19** shall be permitted;
- (b) Physical treatments for disinfection of apiaries such as steam or direct flame shall be permitted;

- (c) the practice of destroying the male brood shall be permitted only to isolate the infestation of Varroa destructor;
- (d) if despite all preventive measures, the colonies become sick or infested, they shall be treated immediately and, if necessary, the colonies may be placed in isolation apiaries;
- (e) 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;
- (f) 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 point 2.5.1. shall apply to those colonies;
- (g) point (f) shall not apply to products authorised for use in organic production pursuant to Article 7 and Article 19.

1.8.6.4. Animal welfare

With regard to **beekeeping** [...], the following additional general rules shall apply:

- (a) the destruction of bees in the combs as a method associated with the harvesting of beekeeping products shall be prohibited;
- (b) mutilation such as clipping the wings of queen bees shall be prohibited.

1.8.6.5. Housing and husbandry practices

With regard to the housing **and husbandry practices**, ~~conditions~~ the following rules shall apply:

- (a) 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;

(b) 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;

(c) 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 or spontaneous vegetation or crops treated with low environmental impact methods equivalent to those as provided for in Articles 28 and 30 of Regulation (EU) No 1305/2013 which cannot affect the qualification of beekeeping production as being organic. These requirements do not apply where flowering is not taking place, or the hives are dormant;

(d) the hives and materials used in beekeeping shall be made basically of natural materials presenting no risk of contamination to the environment or the apiculture products;

~~With regard to beekeeping practices, the following rules shall apply:~~

(e) the beeswax for new foundations shall come from organic production units;

(f) only natural products such as propolis, wax and plant oils may be used in the hives;

(g) the use of chemical synthetic repellents shall be prohibited during honey extraction operations;

(h) the use of brood combs shall be prohibited for honey extraction;

(i) beekeeping shall not be considered as organic when practiced in regions or areas designated by Member States as regions or areas where organic beekeeping is not practicable.

Annex II Part III: Production rules for [...] algae and aquaculture animals

[...]

2. General requirements

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

2.2. Organic and non-organic production units shall be separated adequately and in accordance with the minimum separation distances set by Member States, where such minimum separation distances have been set. 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. [...] **Algae and aquaculture** production shall not be considered as organic when practiced at locations or in areas designated by Member State authorities as locations or areas which are unsuitable for [...] **such activities**.

2.3. 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 control authority or control body. The content of the environmental assessment shall be based on Annex IV to Directive 2011/92/EU of the European Parliament and of the Council⁶⁰. If the **production** unit has already been subject to an equivalent assessment, then its use shall be permitted for this purpose.

2.3a For organic aquaculture production, mangrove destruction shall not be permitted.

⁶⁰ Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1).

2.4. The operator shall provide a sustainable management plan proportionate to the production unit for aquaculture and [...] **algae** harvesting.

2.5. 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.

2.5a. Defensive and preventive measures taken against predators according to Council Directive 92/43/EEC and national rules shall be recorded in the sustainable management plan.

2.5b. Where applicable, coordination shall take place with the neighbouring operators in drawing up the management plan.

2.6. Aquaculture and [...] **algae** business operators shall draw up as part of the sustainable management plan a waste reduction schedule to be put in place at the commencement of operations. Where possible, the use of residual heat shall be limited to energy from renewable sources. [...]

{2.7. Preparation of unprocessed products

If preparation operations, other than processing, are carried out on algae or aquaculture animals, the general requirements laid down in points 1.2., 1.3, 1.4., 1.5 of Part IV shall apply *mutatis mutandis* to such prepared products. }

3. Requirements for [...] algae

In addition to the general production rules laid down in Articles 7, 8, 9 and 12, and where relevant in Section 2, the rules laid down in this Section 3 shall apply to the collection and production of [...] **algae**. Those rules shall apply *mutatis mutandis* to the production of [...] phytoplankton [...].

3.1. Conversion

3.1.1. The conversion period for a [...] **production unit for algae** harvesting shall be six months.

3.1.2. The conversion period for a [...] **production unit** for **algae** cultivation shall be a period of six months or one full production cycle, whichever is the longer.

[...]

3.2. Production rules for [...] **algae**

3.2.1. The collection of wild [...] **algae** and parts thereof [...] is considered as organic production provided that:

(a) the growing areas are of high ecological status as defined by Directive 2000/60/EC⁶¹, **or have a quality equivalent to the production zones classed as A and B in Regulation (EC) No 854/2004⁶²** and are not unsuitable from a health point of view;

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

3.2.2. The cultivation of [...] **algae** shall take place in [...] areas with environmental and health characteristics at least equivalent to those outlined in point 3.2.1(a) in order to be considered organic. In addition the following production rules shall apply:

(a) sustainable practices shall be used in all stages of production, from collection of juvenile [...] **algae** to harvesting;

(b) to ensure that a wide gene-pool is maintained, the collection of juvenile [...] **algae** in the wild shall take place on a regular basis **so as to [...] maintain and increase the diversity of indoor culture stock;**

⁶¹ Directive **2000/60/EC** of the European Parliament and of the Council of **23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1)**.

⁶² **Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.04.2004)**.

(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 **pursuant to Article 19**.

3.3 [...] **Algae** cultivation

3.3.1 [...] **Algae** 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.

3.3.2 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 authorised for use in organic production pursuant to Article 19 may be used.

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

3.3.4 Ropes and other equipment used for growing [...] **algae** shall be re-used or recycled where possible.

3.4 Sustainable harvesting of wild [...] **algae**

3.4.1 A once-off biomass estimate shall be undertaken at the outset of [...] **algae** harvesting

3.4.2 Documentary accounts shall be maintained in the unit or premises and shall enable the operator to identify and the control authority or control body to verify that the harvesters have supplied only wild algae produced in accordance with this Regulation.

3.4.3 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 [...] **algae** can regenerate and by-catches are prevented, such as harvest technique, minimum sizes, ages, reproductive cycles or size of remaining [...] **algae**.

3.4.4. If [...] **algae** is harvested from a shared or common harvest area, documentary evidence **produced by the competent authority designated by the Member State concerned** shall be available, **showing** that the total harvest complies with this Regulation.

4 Requirements for aquaculture animals

In addition to the general production rules laid down in Article 7, 8, 9 and 12, **and where relevant in point 2 of part III of Annex II**, the rules laid down in this point 4 shall apply to *species of* fish, crustaceans, echinoderms and molluscs [...]. Those rules also shall apply *mutatis mutandis* to zooplankton, micro-crustaceans, rotifers, worms and other aquatic feed animals.

4.1 General requirements

4.1.1 Conversion

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;
- (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 producing bivalve molluscs, a conversion period of three months.

[...]

4.1.2 Origin of aquaculture animals

4.1.2.1 With regard to the origin of the aquaculture animals the following rules shall apply:

- (a) organic aquaculture shall be based on the rearing of young stock originating from organic broodstock, and organic [...] **production units**.

(b) locally grown species shall be used and breeding shall aim to give strains which are more adapted to production conditions, ensuring good animal health and welfare and good utilisation of feed resources. Documentary evidence of their origin and treatment shall be provided for the control authority or control body;

(c) species shall be chosen which are robust and can be produced without causing significant damage to wild stocks;

(d) **for breeding purposes**, wild caught or non-organic aquaculture animals may be brought into a holding **only in duly justified cases where no organic breed is available or where new genetic stock for breeding purposes is brought into the production unit after an authorisation has been granted by the competent authority**, with a view to improving the **suitability of** genetic stock. Such animals shall be kept under organic management for at least three months before they may be used for breeding. **For animals that are on the IUCN Red List of endangered species, the authorisation to use wild caught specimens may only be granted in the context of conservation programmes recognised by the relevant public authority in charge of the conservation effort.**

(da) for on growing purposes the collection of wild aquaculture juveniles is specifically restricted to the following cases:

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

(ii) restocking of wild fry or crustacean larvae of species that are not on the IUCN Red List of endangered species in extensive aquaculture farming inside wetlands, such as brackish water ponds, tidal areas and costal lagoons, provided that:

- the restocking is in line with management measures approved by the relevant authorities to ensure the sustainable exploitation of the species concerned, and**
- the animals are fed exclusively with feed naturally available in the environment.**

~~(db).~~ By way of derogation from paragraph (a) ~~[of point 4.1.2.1 in Annex II, Part III],~~ ~~for on-growing purposes~~ Member States may authorise the introduction for on-growing purposes on an organic production unit of a maximum of 50% of non-organic juveniles of species that were not developed as organic in the Union by the date of application of this Regulation, on an aquaculture holding, provided that at least the latter two thirds of the duration of the production cycle is managed under organic management. Such derogation may be granted for a maximum period of ~~2 years~~ and is not renewable.

~~For aquaculture holdings situated outside the Union, such derogation may only be granted by control authorities or control bodies recognised in accordance with Article 29(1) for species that were not developed as organic in the territory of the Country where the holding is located, nor in the Union. Such derogation may be granted for a maximum period of ~~2 years~~ and is not renewable.~~

4.1.2.2 The following rules shall apply with regard to breeding:

- (a) the use of hormones and hormone derivatives shall be prohibited;
- (b) artificial production of monosex strains, except by hand sorting, induction of polyploidy, artificial hybridisation and cloning shall not be used;
- (c) the appropriate strains shall be chosen;

4.1.3 Nutrition

4.1.3.1 With regard to feed for fish and crustaceans and echinoderms: the following rules shall apply:

- (a) animals shall be fed with feed that meets the animal's nutritional requirements at the various stages of its development;
- (b) feeding regimes shall be designed with the following priorities:
 - (i) animal health and welfare;

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

(iii) low environmental impact;

(c) the plant fraction of feed shall [...] **be organic** and the feed fraction derived from aquatic animals shall originate from organic aquaculture or [...] **from fisheries certified as sustainable under a scheme recognised by the competent authority in line with the principles laid down in Regulation (EU) No 1380/2013 of the European Parliament and of the Council**;

(d) [...] non-organic feed materials from plant, **animal, algae or yeast** origin, feed materials [...] of mineral **or of microbial** origin, feed additives [...] and processing aids shall be used only if they have been authorised for use in organic production under this Regulation.

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

[...]

[...]

4.1.3.2 The following rules shall apply with regard to bivalve molluscs and other species which are not fed by man but feed on natural plankton:

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

(b) the growing areas shall be of high ecological status as defined by Directive 2000/60/EC, **or of good environmental status, as defined by Directive 2008/56/EC.**

4.1.3.3 Specific rules on feed for carnivorous aquaculture animals

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

(a) organic feed of aquaculture origin;

- (b) fish meal and fish oil from organic aquaculture trimmings sourced from fish, crustaceans or molluscs;
- (c) fish meal and fish oil and ingredients of fish origin derived from trimmings of fish, crustaceans or molluscs already caught for human consumption in sustainable fisheries;
- (d) fish meal and fish oil and ingredients of fish origin derived from whole fish, crustaceans or molluscs caught in sustainable fisheries and not used for human consumption;
- (e) organic feed materials of plant or animal origin; plant material shall not exceed 60% of total ingredients.

4.1.3.4 Specific rules on feed for certain aquaculture animals

In the grow-out phase, fish in inland waters, penaeid shrimps and freshwater prawns and tropical freshwater fish shall be fed as follows:

- (a) they shall be fed with feed naturally available in ponds and lakes;
- (b) where natural feed is not available in sufficient quantities as referred to in point (a), organic feed of plant origin, preferably grown on the farm itself or algae may be used. Operators shall keep documentary evidence of the need to use additional feed;
- (c) where natural feed is supplemented in accordance with point (b):
 - (i) the feed ration [...] **of shrimps and freshwater prawns (*Macrobrachium* spp.) may comprise a maximum of 25 % fishmeal and 10 % fish oil derived from sustainable fisheries.**
 - (ii) **the feed ration** of siamese catfish (*Pangasius* spp.) may comprise a maximum of 10 % fishmeal or fish oil derived from sustainable fisheries

4.1.4 Health care

4.1.4.1 Disease prevention

With regard to disease prevention the following rules shall apply:

- (a) disease prevention shall be based on keeping the animals in optimal conditions by appropriate siting, taking into account, inter alia, the species' requirements as to good water quality, flow and exchange rate, 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;
- (b) the use of immunological veterinary medicines is allowed;
- (c) an 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 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;
- (d) holding systems, equipment and utensils shall be properly cleaned and disinfected;
- (e) 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;
- (f) only substances for cleaning and disinfection of equipment and facilities authorised for use in organic production pursuant to Article 19 may be used.
- (g) with regard to fallowing the following rules shall apply:
 - (i) the competent authority 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;
 - (ii) it shall not be mandatory for bivalve mollusc cultivation;
 - (iii) during fallowing the cage or other structure used for aquaculture animal production is emptied, disinfected and left empty before being used again;

- (h) 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, minimise disease risks, and to avoid attracting insects or rodents;
- (i) ultraviolet light and ozone may be used only in hatcheries and nurseries;
- (j) for biological control of ectoparasites preference shall be given to the use of cleaner fish **and to the use of freshwater, marine water and sodium chloride solutions.**

4.1.4.2 Veterinary treatments

The following rules shall apply with regard to veterinary treatments:

- (a) disease shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary, under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate. Where appropriate, restrictions with respect to courses of treatment and withdrawal periods shall be defined;
- (b) treatments related to the protection of human and animal health imposed on the basis of Union legislation shall be allowed;
- (c) when despite preventive measures to ensure animal health, according to point 4.1.4.1., a health problem arises, veterinary treatments may be used in the following order of preference:
 - (i) substances from plants, animals or minerals in a homoeopathic dilution;
 - (ii) plants and their extracts not having anaesthetic effects; and
 - (iii) substances such as trace elements, metals, natural immunostimulants or authorised probiotics;

(d) the use of allopathic treatments shall be 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 indicated limits for allopathic treatments are exceeded the aquaculture animals concerned shall not be sold as organic products;

(e) the use of parasite treatments, not including compulsory control schemes operated by Member States, shall be limited to twice per year or once per year where the production cycle is less than 18 months;

(f) the withdrawal period for allopathic veterinary treatments and parasite treatments in accordance with point (d), including treatments under compulsory control and eradication schemes, shall be twice the withdrawal period as referred to in Article 11 of Directive 2001/82/EC or, in a case in which this period is not specified, 48 hours;

(g) whenever veterinary medicinal products are used, such use shall be declared to the control authority or the control body before the animals are marketed as organic. Treated stock shall be clearly identifiable.

4.1.5 Housing conditions and husbandry practices

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

4.1.5.2 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.

4.1.5.3 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 and [...] **have the relevant** stocking density as **laid down in the implementing acts referred to in Article 12(4);**

(b) be kept in water of good quality with, *inter alia*, an adequate flow and exchange rate, sufficient oxygen levels and keeping a low level of metabolites;

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

In considering the effects of the stocking density on the welfare of produced 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 and taken account of.

In the case of freshwater fish, the bottom type shall be as close as possible to natural conditions.

In the case of carp and **similar species**:

- the bottom shall be natural earth;
- **organic and mineral fertilisation of the ponds and lakes shall be carried out with only fertilisers and soil conditioners authorised for use in organic production pursuant to Article 19 with a maximum application of 20 kg nitrogen/ha;**
- **treatments involving synthetic chemicals for the control of hydrophytes and plant coverage present in production waters shall be prohibited.**

4.1.5.4 The design and construction of aquatic containment systems shall provide flow rates and physiochemical parameters that safeguard the animals' health and welfare and provide for their behavioural needs.

The specific characteristics for production and/or containment systems for species or group of species as laid down in the implementing acts referred to in Article 12(4) have to be respected.

4.1.5.5 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 [...] **10 %** of the perimeter ('land-water interface') area shall have natural vegetation.

4.1.5.6 Containment systems at sea shall meet the following conditions:

- (a) they shall be located where water flow, depth and water-body exchange rates are adequate to minimise the impact on the seabed and the surrounding water body;
- (b) they shall have suitable cage design, construction and maintenance with regard to their exposure to the operating environment.

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

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

4.1.5.9 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 algae 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.

[...]

4.1.6 Animal welfare

4.1.6.1 All persons involved in keeping aquaculture animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals.

4.1.6.2 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 minimise physical damage and stress and under anaesthesia where appropriate. Grading operations shall be kept to a minimum and as required to ensure fish welfare.

4.1.6.3 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 produced animals, this maximum shall not exceed **14** 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.

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

4.1.6.5 The use of oxygen is only permitted for uses linked to animal health and welfare 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.

4.1.6.6 Appropriate measures shall be taken to keep the duration of transport of aquaculture animals to a minimum.

4.1.6.7 Any suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.

4.1.6.7a Eyestalk ablation, including all similar practices such as ligation, incision and pinching, is prohibited.

4.1.6.8 Slaughter techniques shall render fish immediately unconscious and insensible to pain. Handling prior to slaughter shall be performed in a way that avoids injuries while keeping suffering and stress at a minimum. Differences in harvesting sizes, species, and production sites must be taken into account when considering optimal slaughtering methods.

4.2 [...] **Detailed** rules for molluscs

4.2.1 Origin of seed

With regard to the origin of seed the following rules shall apply:

- (a) wild seed from outside the boundaries of the production unit may be used in the case of bivalve shellfish, provided that there is no significant damage to the environment, it is permitted by local legislation and the wild seed comes from:
 - (i) settlement beds which are unlikely to survive winter weather or are surplus to requirements; or
 - (ii) natural settlement of shellfish seed on collectors;
- (b) for the cupped oyster, *Crassostrea gigas*, preference shall be given to stock which is selectively bred to reduce spawning in the wild;
- (c) records shall be kept of how, where and when wild seed was collected to allow traceability back to the collection area. **Wild seed may be collected only after the authorisation has been granted by the competent authority.**

4.2.2 Housing conditions and husbandry practices

With regard to the housing conditions and husbandry practices the following rules shall apply:

- (a) production may be carried out in the same area of water as organic finfish and [...] **algae** production 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;
- (b) 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;
- (c) 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.

4.2.3 Cultivation -

With regard to cultivation the following rules shall apply:

(a) cultivation on mussel ropes and other methods listed in [...] **the implementing acts referred to in Article 12(4)** may be eligible for organic production;

(b) bottom cultivation of molluscs is only permitted where no significant environmental impact is caused at the collection and growing sites. A survey and report supporting the evidence of minimal environmental impact shall be added as a separate chapter to the sustainable management plan and provided by the operator to the control authority or control body before starting operations.

4.2.4 Management

With regard to management the following rules shall apply:

(a) production shall use a stocking density not in excess of that used for non-organic molluscs 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;

(b) biofouling organisms shall be removed by physical means or by hand and where appropriate returned to the sea away from mollusc farms. Molluscs may be treated once during the production cycle with a lime solution to control competing fouling organisms.

4.2.5 Specific cultivation rules for oysters

Cultivation in bags on trestles shall be 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 requirements set out in [...] **the implementing acts as referred to in Article 12(4)**

Annex II, Part IV: Processed food [...] production rules

In addition to the general production rules laid down in Articles 7, 9 and 13, the rules laid down in this Part shall apply to processed food [...].

1. General requirements for the production of processed food [...].

1.1 Food ~~and feed~~ 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 practice⁶³.

1.2. Operators producing processed food [...] shall establish and update appropriate procedures based on a systematic identification of critical processing steps.

1.3 The application of the procedures referred to in point 1.2. shall guarantee at all times that the produced processed products comply with this Regulation.

1.4 Operators shall comply with and implement the procedures referred to in point 1.2., and in particular shall ~~f~~without prejudice to Article 20a⁶⁴~~t~~:

~~f~~(a) take ~~preventive and~~ precautionary measures to avoid the risk of contamination by ~~unauthorised substances or products⁶⁵~~~~t~~;

(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 organic production.

⁶³ Good manufacturing practices (GMPs) as defined in Article 3(a) of Commission Regulation (EC) N° 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (O.J. L 384, 29.12.2006, p. 75)

~~⁶⁴ — A list T18~~

~~⁶⁵ — A list T18~~

1.5 The preparation of processed organic products shall be kept separate in time or space from non-organic products. When non-organic products are also prepared or stored in the preparation unit concerned, the operator shall:

- (a) inform the control authority or control body accordingly;
- (b) 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;
- (c) store organic products, before and after the operations, separate by place or time from non-organic products;
- (d) keep available an updated register of all operations and quantities processed;
- (e) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with non-organic products;
- (f) carry out operations on organic products only after suitable cleaning of the production equipment.

1.6 Products, 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 organic food or that otherwise may be misleading as to the true nature of products intended to be marketed as organic food shall not be used.

2. **Detailed** requirements for the production of processed food

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

- (a) the product shall be produced mainly from agricultural ingredients **and/or products intended for use as food listed in Annex I**; in order to determine whether a product is produced mainly from [...] **those products**, added water and salt shall not be taken into account;

[...]

(c) an organic ingredient shall not be present together with the same ingredient in [...] non-organic form;

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

[...]

2.2. [...] Use of certain products and substances in processing of food

2.2.1. Only [...] **those food additives, processing aids and non-organic agricultural ingredients authorised for use in organic production pursuant to Article 19 or Article 19aa**, as well as the products and substances referred to in point 2.2.2 [...] may be used in the processing of food, with the exception of products and substances of the wine sector, for which point 2 of Part V shall apply, and of yeast for which point 1.3 of Part VI shall apply

2.2.2 In the processing of food, the use of the following products and substances shall be allowed:

(a) preparations of micro-organisms and food enzymes normally used in food processing; however food enzymes to be used as food additives have to be authorised for use in organic production pursuant to Article 19;

{(b) substances, and products as defined in Article 3(2)(c) and (d)(i) of Regulation (EC) No 1334/2008 of the European Parliament and of the Council labelled as natural flavouring substances or natural flavouring preparations, in accordance with Articles 15(1) (e) and 16 **(2), (3) and (4)** of that Regulation,⁶⁶}

(c) colours for stamping meat and eggshells in accordance with Article 17 of Regulation (EC) No 1333/2008 of the European Parliament and of the Council⁶⁷;

⁶⁶ ~~A list T18~~

⁶⁷ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

(ca) natural colours and natural coating substances 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;

(d) drinking water and **organic or non-organic** salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;

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

~~*f(ee) minerals (trace elements included), vitamins, aminoacids, and micronutrients only authorised as far as their use is legally required in the foodstuffs in which they are incorporated as well as to fulfil the specific nutritional to fulfil dietary requirements in the case of requirements for food intended for infants and young children in the sense of and food for special medical purposes in accordance with Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013.*~~

f(e) Minerals (trace elements included), vitamins, aminoacids and micronutrients, only authorised:

(i) when their use in food for normal consumption is directly legally required by provisions of Union law or provisions of national law compatible with Union law, with the consequence that the food cannot be placed at all on the market as food for normal consumption if the mineral, vitamin, aminoacid or micronutrient is not added;

or

(ii) as regards food placed on the market as having particular characteristics or effects in relation to health or nutrition or in relation to needs of specific groups of consumers, in food regulated by Commission Directive 2006/141/EC⁶⁸ or Commission Directive 2006/125/EC⁶⁹ provided that their use is authorised by these Directives⁷⁰.

2.2.3 For the purpose of tarhe calculation referred to in Article 21(3), the following rules shall apply:

- (a) certain food additives authorised for use in organic production pursuant to Article 19 shall be calculated as agricultural ingredients;
- (b) preparations and substances referred to in **points (a), (c), (d) and (e) of point 2.2.2.** shall not be calculated as agricultural ingredients;
- (c) yeast and yeast products shall be calculated as agricultural ingredients.

[...]

[...]

‡2.2.5a. For the processing of organic flavours the following additional requirements shall be fulfilled:

- (a) only flavouring extracts and natural flavourings as defined in Article 16(4) and (5) of Regulation (EC) No 1334/2008 of the European Parliament and of the Council⁷¹ shall be considered as organic flavourings;**

⁶⁸ **Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, OJ L 401, 30.12.2006, p. 1–33 (will be repealed as of February 2020 by Commission Delegated Regulation 2016/127)**

⁶⁹ **Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children, OJ L 339, 6.12.2006, p. 16–35**

⁷⁰ **Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children, OJ L 339, 6.12.2006, p. 16–35**

⁷¹ *Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).*

- (b) for organic flavourings, 95% of flavour components shall be organic;**
- (c) only organic carriers shall be allowed and included in the calculation of the percentage of agricultural ingredients;**
- (d) additives, solvents and processing aids shall be used in organic form when available.†**

Part IVa : Processed feed production rules

In addition to the general production rules laid down in Articles 7, 9 and 13~~ab~~, the rules laid down in this Part shall apply to processed feed.

1. General requirements for the production of processed feed

1.1. Feed additives, processing aids and other substances and ingredients used for processing feed and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice.

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

1.3. The application of the procedures referred to in point 1.2. shall guarantee at all times that the produced processed products comply with this Regulation.

1.4. Operators shall comply with and implement the procedures referred to in point 1.2., and in particular shall ~~take~~ *without prejudice to Article 20a⁷²*:

(a) ~~take preventive and precautionary measures to avoid the risk of contamination by unauthorised substances or products⁷³~~;

(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 organic production.

⁷² — A list T18

⁷³ — A list T18

1.5 The preparation of processed organic products shall be kept separate in time or space from non-organic products. When non-organic products are also prepared or stored in the preparation unit concerned, the operator shall:

- (a) inform the control authority or control body accordingly;**
- (b) 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;**
- (c) store organic products, before and after the operations, separate by place or time from non-organic products;**
- (d) keep available an updated register of all operations and quantities processed;**
- (e) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with non-organic products;**
- (f) carry out operations on organic products only after suitable cleaning of the production equipment.**

2. Detailed requirements for the production of processed feed

2.1 Organic feed materials, or in-conversion feed materials, shall not enter simultaneously with the same feed materials produced by non-organic means into the composition of the organic feed product.

2.2 Any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesised solvents.

2.3 Only non –organic feed material of plant origin, feed material of animal and mineral origin, feed additives and processing aids authorised for use in organic production pursuant to Article 19, may be used in the processing of feed.

PART V: Wine

1. Scope

1.1. In addition to the general production rules laid down in Articles 7, 8, 9, 13 and 14, the rules laid down in this Part shall apply to the organic production of the products of the wine sector as referred to in point (1) of Article 1(2) of Regulation (EU) No 1308/2013.

1.2 Commission Regulations (EC) No 606/2009⁷⁴ and (EC) No 607/2009⁷⁵ shall apply, save as explicitly provided otherwise in this Part.

2. Use of certain products and substances

2.1 Products of the wine sector shall be produced from organic raw material.

2.2 Only products and substances authorised for use in organic production pursuant to Article 19 may 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 (EU) No 1308/2013 and Regulation (EC) No 606/2009 and in particular in Annex I A to that Regulation.

{3. Oenological practices and restrictions⁷⁶}

⁷⁴ Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions (OJ L 193, 24.7.2009, p. 1).

⁷⁵ Commission Regulation (EC) No 607/2009 of 14 July 2009 laying down certain detailed rules for the implementation of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products (OJ L 193, 24.7.2009, p. 60).

⁷⁶ ~~A list T18~~

3.1 Without prejudice to Sections 1. and 2. and to specific prohibitions and restrictions provided for in points 3.2 to 3.5, only oenological practices, processes and treatments, including the restrictions provided for in Article 80 and 83(2) of Regulation (EU) No 1308/2013, and in Article 3, Articles 5 to 9 and Articles 11 to 14 of Regulation (EC) No 606/2009, and in the Annexes to those Regulations, used before 1 August 2010, shall be permitted.

3.2. The use of the following oenological practices, processes and treatments shall be prohibited:

(a) partial concentration through cooling according to point (c) of Section B.1 of Part I of Annex VIII to Regulation (EU) No 1308/2013;

(b) elimination of sulphur dioxide by physical processes according to point 8 of Annex I A to Regulation (EC) No 606/2009;

(c) electro dialysis 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.

3.3 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 {75} °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.

~~3.4 The use of the following oenological practices, processes and treatments shall be re-examined by the Commission before 1 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 I A to Regulation (EC) No 606/2009;~~

~~(b) use of ion exchange resins as referred to in point 20 of Annex I A to Regulation (EC) No 606/2009;~~

~~(c) reverse osmosis according to point (b) of Section B.1 of Part I of Annex VIII to Regulation (EU) No 1308/2013.~~

3.5 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 authorisation of the measures in this Section 3 and, if required, an evaluation according to Article 19 of this Regulation.

Annex II, Part VI: Yeast used as food or feed

In addition to the general production rules laid down in Articles 7, 9, **13, 13~~ab~~** and 15, the rules laid down in this Part shall apply to organic yeast used as food or feed.

1 General requirements

1.1 For the production of organic yeast only organically produced substrates shall be used.

However, until 31 December 2020, the addition of up to 5 % non-organic yeast extract or autolysate to the substrate (calculated in weight of dry matter) is allowed for the production of organic yeast, where operators are unable to obtain yeast extract or autolysate from organic production.

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

1.3 The following substances may be used in the production, confection and formulation of organic yeast:

- (a) processing aids authorised for use in organic production pursuant to Article 19;
- (b) products and substances referred to in point 2.2.2. (a) and (d) of Part IV.

COLLECTION, PACKAGING, TRANSPORT AND STORAGE OF PRODUCTS

1 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 control authority or control body.

2 Packaging and transport of products to other operators or units

2.1 Operators shall ensure that organic products are transported to other operators or 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 Union 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 organic production;
- (c) the name or the code number of the control authority or control 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 control authority or control body and which permits to link the lot with the records referred to in Article 24.

The information referred to in points (a) to (d) 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 or the transporter.

2.2 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;
- (b) the products are accompanied by a document giving the information required under point 2.1; and
- (c) both the expediting and the receiving operators keep documentary records of such transport operations available for the control authority or control body.

3 Special rules for transporting feed to other production or preparation units or storage premises

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) vehicles or containers which have transported non-organic products may only be used to transport organic products if:
 - (i) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before commencing the transport of organic products and the operators record these operations;
 - (ii) all appropriate measures are implemented, depending on the risks evaluated in accordance with control arrangements 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 keep documentary records of such transport operations available for the control authority or control 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.

4 Transport of live fish

- 4.1 Live fish shall be transported in suitable tanks with clean water which meets their physiological needs in terms of temperature and dissolved oxygen.
- 4.2 Before transport of organic fish and fish products, tanks shall be thoroughly cleaned, disinfected and rinsed.
- 4.3 Precautions shall be taken to reduce stress. During transport, the density shall not reach a level which is detrimental to the species.
- 4.4 Documentary evidence shall be maintained for operations referred to in points 4.1, 4.2 and 4.3.

5 Reception of products from other operators of units

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 for in Section 2.

The operator shall crosscheck the information on the label referred to in Section 2 with the information on the accompanying documents. The result of those verifications shall be explicitly mentioned in the records referred to in Article 24.

6 Special rules for the reception of products from a third country

Where organic products are imported from a third country, they shall be transported in appropriate packaging or containers, closed in a manner preventing substitution of the content and provided with identification of the exporter and with any other marks and numbers serving to identify the lot and with the certificate of control for import from third countries as appropriate.

On receipt of an organic product imported from a third country, the natural or legal person to whom the imported consignment is delivered and who receives it for further preparation or marketing, shall check the closing of the packaging or container and, in the case of products imported in accordance with Article 28(1)(b)(ii), shall check that the certificate of inspection referred to in that Article covers the type of product contained in the consignment. The result of this verification shall be explicitly mentioned in the records referred to in Article 24.

7 Storage of products

7.1 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 or substances not in compliance with the organic production rules. Organic products shall be clearly identifiable at all times.

7.2 In case of organic plant and livestock production units, storage of input products other than those authorised for use in organic production pursuant to Article 19 is prohibited in the production unit.

7.3 The storage of allopathic veterinary medicinal products and antibiotics is permitted on agricultural and aquaculture holdings provided that they have been prescribed by a veterinarian in connection with treatment as referred to in points 1.5.2.2 of Part II and 4.1.4.2(a) of Part III of Annex II, that they are stored in a supervised location and that they are entered in the livestock record as referred to in Article 24.

7.4 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 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 and the operators shall record these operations.
-

TERMS REFERRED TO IN ARTICLE 21

- BG: биологичен.
- ES: ecológico, biológico, **orgánico.**
- CS: ekologické, biologické.
- DA: økologisk.
- DE: ökologisch, biologisch.
- ET: mahe, ökoloogiline.
- EL: βιολογικό.
- EN: organic.
- FR: biologique.
- GA: orgánach.
- HR: ekološki.
- IT: biologico.
- LV: bioloģisks, ekoloģisks.
- LT: ekologiškas.
- LU: ***biologesch, ökologesch.***
- HU: ökológiai.

MT: organiku.

NL: biologisch.

PL: ekologiczne.

PT: biológico.

RO: ecologic.

SK: ekologické, biologické.

SL: ekološki.

FI: luonnonmukainen.

SV: ekologisk.



ORGANIC PRODUCTION LOGO OF THE EUROPEAN UNION AND CODE NUMBERS

1 Logo

1.1 The organic production logo of the European Union shall comply with the model below:

LOGO to be inserted

1.2 The reference colour in Pantone is Green Pantone No 376 and Green (50 % Cyan + 100 % Yellow), when a four-colour process is used.

1.3 The organic production logo of the European Union may also be used in black and white as shown, only where it is not practicable to apply it in colour:

LOGO to be inserted

1.4 If the background colour of the packaging or label is dark, the symbols may be used in negative format, using the background colour of the packaging or label.

1.5 If a logo is used in colour on a coloured background, which makes it difficult to see, a delimiting outer line around the logo can be used to improve contrast with the background colours.

1.6 In certain specific situations where there are indications in a single colour **on the packaging, the organic production logo of the European Union may be used in the same colour.**

1.7 The organic production logo of the European Union must have a height of at least 9 mm and a width of at least 13,5 mm; the proportion ratio height/width shall always be 1:1,5. Exceptionally the minimum size may be reduced to a height of 6 mm for very small packages.

1.8. The organic production logo of the European Union may be associated with graphical or textual elements referring to organic production, under the condition that they do not modify or change the nature of the organic production logo of the European Union, nor any of the indications defined in accordance with Article 22. When associated to national or private logos using a green colour different from the reference colour provided for in point 1.2, the organic production logo of the European Union may be used in that non-reference colour.

2 Code numbers

The general format of the code numbers shall be as follows:

AB-CDE-999

Where:

- (a) 'AB' is the ISO code for the country where the controls take place;
- (b) 'CDE' is a term, indicated in three letters to be decided by the Commission or each Member State, like "bio" or "öko" or "org" or "eko" establishing a link with organic production; and
- (c) '999' is the reference number, indicated in maximum three digits, to be assigned by:
 - (i) each Member State's competent authority to the control authorities or control bodies to which they have delegated control tasks;
 - (ii) the Commission, to:
 - the control authorities and control bodies recognised by the Commission pursuant to of Article 29;
 - to the competent authorities of third countries recognised by the Commission pursuant to of Article 31.

~~ANNEX Va~~

~~Specific tasks of the Commission, Member States and the competent Union authorities~~

- ~~— identification and analysis of gaps and deficiencies in the supply of inputs (organically bred seeds, feed and livestock);~~
- ~~— monitoring of the organic sector, scientific findings and consultations with stakeholders in the sector and other interested parties;~~
- ~~— collection, analysis and hosting of relevant scientific and technical data as specified in and relevant for the implementation of this Regulation in Member States and in third countries;~~
- ~~— facilitation of the requirements for controls by competent authorities and bodies and for supervision of the recognition of control bodies and control authorities within the Union and in third countries;~~
- ~~— monitoring and coordination of the European organic action plan, including development of the organic seed sector and the market for organic feed;}~~

~~ANNEX V~~

{ANNEX Vd - Certificate

Model of the certificate according to Article 25(0a)1 of Regulation (EU) No XXX/XXX [Organic production and labelling of organic products Regulation]⁷⁷ }

1. Document number:	
2. (tick one box as appropriate) <input type="checkbox"/> Operator <input type="checkbox"/> Group of operators - see annex I	3. Name and address of operator or group of operators:
4. Activit(y)(ies) of the operator or group of operators (choose as appropriate): <input type="checkbox"/> Agricultural production <input type="checkbox"/> Preparation <input type="checkbox"/> Distribution <input type="checkbox"/> Storing <input type="checkbox"/> Import <input type="checkbox"/> Export <input type="checkbox"/> Placing on the market	5. Name, address and code number of control authority or control body of the operator or group of operators:

⁷⁷ — A list T18

<p>6. Categor(y)(ies) of products as referred to in Article 25(5a) of Regulation (EU) No XXX/XXX and production methods (choose as appropriate):</p>	
<p>– unprocessed plants and plant products, including seed and other plant reproductive material</p> <p>Defined as:</p> <p><input type="checkbox"/> organic production</p> <p><input type="checkbox"/> production of in-conversion products</p> <p><input type="checkbox"/> with non-organic production (pursuant to Article 7(3) of Regulation (EU) No XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</p>	<p>Certificate validity period from to</p>
<p>– livestock and unprocessed livestock products</p> <p>Defined as:</p> <p><input type="checkbox"/> organic production</p> <p><input type="checkbox"/> production of in-conversion products</p> <p><input type="checkbox"/> with non-organic production (pursuant to Article 7(3) of Regulation (EU) No XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</p>	<p>Certificate validity period from to</p>

<p>– algae and unprocessed aquaculture products</p> <p>Defined as:</p> <p><input type="checkbox"/> organic production</p> <p><input type="checkbox"/> production of in-conversion products</p> <p><input type="checkbox"/> with non-organic production (pursuant to Article 7(3) of Regulation (EU) No XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</p>	<p>Certificate validity period from to</p>
<p>– processed agricultural products, including aquaculture products, for use as food</p> <p>Defined as:</p> <p><input type="checkbox"/> organic production</p> <p><input type="checkbox"/> production of in-conversion products</p> <p><input type="checkbox"/> with non-organic production (pursuant to Article 7(3) of Regulation (EU) No XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</p>	<p>Certificate validity period from to</p>
<p>– Feed</p> <p>Defined as:</p> <p><input type="checkbox"/> organic production</p> <p><input type="checkbox"/> production of in-conversion products</p> <p><input type="checkbox"/> with non-organic production (pursuant to Article 7(3) of Regulation (EU) No XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</p>	<p>Certificate validity period from to</p>

<p>– Wine</p> <p>Defined as:</p> <p><input type="checkbox"/> organic production</p> <p><input type="checkbox"/> production of in-conversion products</p> <p><input type="checkbox"/> with non-organic production (pursuant to Article 7(3) of Regulation (EU) No XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</p>	
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<p>– Other products listed in Annex I to the Regulation (EU) No XXX/XXX [Organic production and labelling of organic products Regulation] or not covered by previous categories (<i>please specify</i>):</p> <p>Defined as:</p> <p><input type="checkbox"/> organic production</p> <p><input type="checkbox"/> production of in-conversion products</p> <p><input type="checkbox"/> with non-organic production (pursuant to Article 7(3) of Regulation (EU) No XXX/XXX or in case of preparation, distribution, storing, import, export, placing on the market)</p>	
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This document has been issued in accordance with the provisions of Regulation (EU) No XXX/XXX [Organic production and labelling of organic products Regulation] to certify that the operator or group of operators (choose as appropriate) meets the requirements of that Regulation.

Date, place

Signature on behalf of the issuing control authority or control body:

**Annex – List of members of Group of operators as defined in Article 26 of Regulation (EU)
No XXX/XXX**

(iv)Name of member	(v) Address
(vi)	(vii)
(viii)	(ix)
(x)	(xi)

Declaration from the Commission

The Commission acknowledges the need to establish conditions under which organic varieties suitable for organic production shall be developed.

For the purpose of establishing criteria for the description of the characteristics of ‘organic varieties suitable for organic production’, as well as defining the conditions under which ‘organic varieties suitable for organic production’ may be produced with a view to marketing, the Commission will organise at the latest 6 months after the date of application of the present Regulation a temporary experiment.

This temporary experiment will establish criteria for describing the distinctness, uniformity, stability, and, where applicable, the value for cultivation and use of organic varieties suitable for organic production and address other marketing conditions such as labelling and packaging. These conditions and criteria will take into account the specific needs and aims of organic agriculture such as enhancing genetic diversity, disease resistance and adaptation to soil and climate conditions. Yearly reports will be produced to monitor the progress of the temporary experiment

In the framework of such an experiment, which shall have a term of seven years and foresee sufficient quantities, Member States may be released from certain obligations laid down in Directive 66/401/EEC, Directive 66/402/EEC, Directive 68/193/EEC, Directive 2002/53/EC, Directive 2002/54/EC, Directive 2002/55/EEC, Directive 2002/56/EEC, Directive 2002/57/EEC, Directive 2008/72/EEC and Directive 2008/90/CE.

The Commission will assess the result of this experiment with a view to propose the amendment of the requirements of the horizontal legislation on the marketing of seeds and other plant reproductive materials to the characteristics of the ‘organic varieties suitable for organic production’.