

ANNEX II

DETAILED PRODUCTION RULES REFERRED TO IN CHAPTER III**Part IV: Processed food production rules**

In addition to the general production rules laid down in Articles 9, 11 and 16, the rules laid down in this Part shall apply to the organic production of processed food.

1. General requirements for the production of processed food
 - 1.1. Food additives, processing aids and other substances and ingredients used for processing food and any processing practice applied, such as smoking, shall comply with the principles of good manufacturing practice⁽¹⁾.
 - 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 ensure that the produced processed products comply with this Regulation at all times.
 - 1.4. Operators shall comply with and implement the procedures referred to in point 1.2, and, without prejudice to Article 28, shall in particular,:
 - (a) take precautionary measures;
 - (b) implement suitable cleaning measures, monitor their effectiveness and keep records of those operations;
 - (c) guarantee that non-organic products are not placed on the market with an indication referring to organic production.
 - 1.5. The preparation of processed organic, in-conversion and non-organic products shall be kept separate from each other in time or space. Where organic, in-conversion and non-organic products, in any combination, are prepared or stored in the preparation unit concerned, the operator shall:
 - (a) inform the competent authority, or, where appropriate, the control authority or control body, accordingly;
 - (b) carry out the operations continuously until the production run has been completed, separately in place or time from similar operations performed on any other kind of product (organic, in-conversion or non-organic);
 - (c) store organic, in-conversion and non-organic products, before and after the operations, separate by place or time from each other;
 - (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 between organic, in-conversion and non-organic products;
 - (f) carry out operations on organic or in-conversion 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.

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2. Detailed requirements for the production of processed food
- 2.1. The following conditions shall apply to the composition of processed organic food:
 - (a) the product shall be produced mainly from agricultural ingredients or products intended for use as food listed in Annex I; for the purpose of determining whether a product has been produced mainly from those products, added water and salt shall not be taken into account;
 - (b) an organic ingredient shall not be present together with the same ingredient in non-organic form;
 - (c) 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 food additives, processing aids and non-organic agricultural ingredients authorised pursuant to Article 24 or Article 25 for use in organic production, and 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 VI shall apply, and with the exception of yeast, for which point 1.3 of Part VII shall apply.
- 2.2.2. In the processing of food, the following products and substances may be used:
 - (a) preparations of micro-organisms and food enzymes normally used in food processing, provided that food enzymes to be used as food additives have been authorised pursuant to Article 24 for use in organic production;
 - (b) substances and products defined in points (c) and (d)(i) of Article 3(2) of Regulation (EC) No 1334/2008 that have been labelled as natural flavouring substances or natural flavouring preparations in accordance with Article 16(2), (3) and (4) of that Regulation;
 - (c) colours for stamping meat and eggshells in accordance with Article 17 of Regulation (EC) No 1333/2008;
 - (d) natural colours and natural coating substances for the traditional decorative colouring of the shell of boiled eggs produced with the intention of placing them on the market at a given period of the year;
 - (e) drinking water and organic or non-organic salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;
 - (f) minerals (trace elements included), vitamins, amino acids and micronutrients, provided that:
 - (i) their use in food for normal consumption is ‘directly legally required’, in the meaning of being directly 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 those minerals, vitamins, amino acids or micronutrients are not added; or

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- (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 products referred to in points (a) and (b) of Article 1(1) of Regulation (EU) No 609/2013 of the European Parliament and of the Council⁽²⁾ their use is authorised by that Regulation and acts adopted on the basis of Article 11(1) of that Regulation for the products concerned, or
 - in products regulated by Commission Directive 2006/125/EC⁽³⁾, their use is authorised by that Directive.
- 2.2.3. Only the products for cleaning and disinfection authorised pursuant to Article 24 for use in processing shall be used for that purpose.
- 2.2.4. For the purpose of the calculation referred to in Article 30(5), the following rules shall apply:
 - (a) certain food additives authorised pursuant to Article 24 for use in organic production shall be calculated as agricultural ingredients;
 - (b) preparations and substances referred to in points (a), (c), (d), (e) and (f) of point 2.2.2 shall not be calculated as agricultural ingredients;
 - (c) yeast and yeast products shall be calculated as agricultural ingredients.

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- (1) Good manufacturing practices (GMPs) as defined in Article 3(a) of Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food ([OJ L 384, 29.12.2006, p. 75](#)).
- (2) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 ([OJ L 181, 29.6.2013, p. 35](#)).
- (3) 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](#)).

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