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Production rules for processed food - Regulation (EU) 2018/848, Art. 16 and Annex II Part IV

加工食品生产规则——法规(EU) 2018/848, 第 16 条和附录二第四部分

Art. 16 第 16	Operators that produce processed food shall comply, in particular, with the detailed production rules set out in Part IV of Annex II and in any implementing acts referred to in paragraph 3 of this Article. 生产加工食品的操作者尤其应遵守附件二第四部分规定的详细生产规则以及本条第 3 款所述的任何实施法案。
Annex II Part IV 附录二第四部分	
	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 除第 9、11 和 16 条规定的通用生产规则外，本部分规定的规则还适用于加工食品的有机生产。
1.	General requirements for the production of processed food 加工食品生产的通用要求
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. 食品添加剂、加工助剂和其他用于加工食品的物质和成分以及所采用的任何加工操作，如烟熏，应符合良好生产规范的原则。
1.2.	Operators producing processed food shall establish and update appropriate procedures based on a systematic identification of critical processing steps. 生产加工食品的操作者应在系统识别关键加工步骤的基础上，建立和更新适当的程序。
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. 应用第 1.2 点所述程序，应确保所生产的加工产品始终符合本法规的要求。

1.4.	<p>Operators shall comply with and implement the procedures referred to in point 1.2, and, without prejudice to Article 28 shall in particular:</p> <p>操作者应遵守并实施第 1.2 点中提到的程序，并且在不影响第 28 条的情况下，特别应：</p>
	<p>(a) take precautionary measures and keep records of those measures 采取预防措施并记录这些措施</p>
	<p>(b) implement suitable cleaning measures, monitor their effectiveness and keep records of those operations 实施适当的清洁措施，监测其有效性，并记录这些操作</p>
	<p>(c) guarantee that non-organic products are not placed on the market with an indication referring to organic production 保证非有机产品在投放市场时不会被标识为有机生产</p>
1.5.	<p>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:</p> <p>有机加工产品、转换期产品和非有机产品的制备应在时间或空间上相互分离。如果在相关制备单元中制备或储存有机、转换和非有机产品时，操作者应：</p>
	<p>(a) inform the competent authority, or, where appropriate, the control authority or control body, accordingly 通知相关的主管部门，或在适当情况下通知监管机构或控制机构</p>
	<p>(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) 执行连续操作，直到生产运行完成，与对任何其他类型产品（有机、转换或非有机）进行的类似操作分开地点或时间进行</p>
	<p>(c) store organic, in-conversion and non-organic products, before and after the operations, separate by place or time from each other 在操作前后按地点或时间将有机产品、转换期产品和非有机产品分开贮存</p>
	<p>(d) keep available an updated register of all operations and quantities processed 保持所有操作和处理数量的最新登记册</p>
	<p>(e) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges between organic, in-conversion and non-organic products 采取必要措施确保批次识别，避免有机产品、转换产品和非有机产品之间的混合或交换</p>

	(f) carry out operations on organic or in-conversion products only after suitable cleaning of the production equipment 仅在对生产设备进行适当清洁后，才能对有机产品或转换产品进行操作
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. 不得使用重建有机食品加工和储存过程中损失的特性、纠正有机食品加工过程中疏忽造成的结果或可能对销售产品的真实性产生误导的产品、物质和技术。
1.7.	Operators shall keep available documentary evidence on authorisations for the use of non-organic agricultural ingredients for the production of processed organic food in accordance with Article 25 if they have obtained or used such authorisations. 操作者应保留符合第 25 条规定的授权使用非有机农业成分进行有机食品加工的授权证明文件。
2.	Detailed requirements for the production of processed food 加工食品生产的具体要求
2.1.	The following conditions shall apply to the composition of processed organic food: 下列条件适用于加工有机食品的成分：
	(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 该产品应主要由农业原料或拟用作附录一所列食品的产品生产；为了确定产品是否主要由这些产品生产，不应考虑添加的水和盐；
	(b) an organic ingredient shall not be present together with the same ingredient in non-organic form 相同成分不得同时存在有机与非有机形式；
	(c) an in-conversion ingredient shall not be present together with the same ingredient in organic or non-organic form 相同成分不得同时存在转换、有机或非有机形式；
2.2.	Use of certain products and substances in processing of food 在食品加工中的使用某些产品和物质

2.2.1.	<p>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 and Articles 4 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.</p> <p>只有根据第 24 条或第 25 条授权用于有机生产的食品添加剂、加工助剂和非有机农业成分，以及第 2.2.2 点和第 4 条所述的产品和物质可用于食品加工，但葡萄酒行业的产品和物质除外，第六部分第 2 点适用，酵母除外，第七部分第 1.3 点适用。</p>
2.2.2.	<p>In the processing of food, the following products and substances may be used:</p> <p>在食品加工过程中，可使用以下产品和物质：</p>
	<p>(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</p> <p>在食品加工过程中通常使用微生物制剂和食品酶，前提是用作食品添加剂的食品酶根据第 24 条法规已获得授权用于有机生产</p>
	<p>(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</p> <p>符合第 1334/2008 号法规 (EC) 第 3 (2) 条第 (c) 点和第 (d) (i) 点中定义的食品物质和产品，已根据该法规第 16 (2) 、 (3) 和 (4) 条标识为天然香料或天然调味剂</p>
	<p>(c) colours for stamping meat and eggshells in accordance with Article 17 of Regulation (EC) No 1333/2008</p> <p>符合第 1333/2008 号法规 (EC) 第 17 条规定用于肉类和蛋壳盖章的着色物质</p>
	<p>(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</p> <p>在一年中的特定时期投放市场的煮蛋外壳进行传统装饰的天然色素和天然涂层物质</p>
	<p>(e) drinking water and organic or non-organic salt (with sodium chloride or potassium chloride as basic components) generally used in food processing</p> <p>在食品加工中常用的饮用水和有机或非有机盐（基本成分为氯化钠或氯化钾为）</p>
	<p>(f) minerals (trace elements included), vitamins, amino acids and micronutrients may be used, provided that:</p> <p>可使用矿物质（包括微量元素）、维生素、氨基酸和微量营养素，前提是：</p>

	<p>(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 它们在正常食用的食品中的使用是“应法律要求的”，即联邦法律或与联邦法律兼容的国家法律直接要求的。因此，如果不添加这些矿物质、维生素、氨基酸或微量营养素，这些食品根本无法作为正常消费食品投放市场。</p>
	<p>(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 关于投放市场的食品在健康或营养方面或在特定消费者群体的需求方面具有特定特征或影响。</p>
2.2.3.	<p>Only the products for cleaning and disinfection authorised pursuant to Article 24 for use in processing shall be used for that purpose. Operators shall keep records of the use of those products, including the date or dates on which each product was used, the name of the product, its active substances and the location of such use. 只有根据第 24 条授权用于加工的清洁和消毒产品才能用于此目的。操作者应记录这些产品的使用情况，包括每种产品的使用日期、产品名称、活性物质和使用地点。</p>
2.2.4.	<p>For the purpose of the calculation referred to in Article 30(5), the following rules shall apply: 就第 30 (5) 条所述的计算而言，应适用以下规则：</p>
	<p>(a) certain food additives authorised pursuant to Article 24 for use in organic production shall be calculated as agricultural ingredients 根据第 24 条授权用于有机生产的某些食品添加剂应计入农业成分</p>
	<p>(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 第 2.2.2 条第 (a)、(c)、(d)、(e) 和 (f) 点所说的制剂和物质不得计入农业成分</p>
	<p>(c) yeast and yeast products shall be calculated as agricultural ingredients. 酵母和酵母制品应计入农业成分。</p>
2.2.5.	<p>Operators shall keep records of any input used in the food production. In case of production of composite products, complete recipes/formulae showing the quantities of input and output shall be kept available for the competent authority or control body. 操作者应记录食品生产中使用的任何投入品。在生产多配方产品的情况下，应向主管当局或认证机构提供显示投入和产出数量的完整配方/公式。</p>