

temporary experiment should be organised in accordance with Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC. That temporary experiment should be for a term of seven years, should involve sufficient quantities of plant reproductive material and should be subject to yearly reporting. It should help to establish the criteria for the description of the characteristics of that material and to determine the production and marketing conditions for that material.

- (40) As livestock production naturally involves the management of agricultural land, where manure is used to nourish crop production, landless livestock production should be prohibited, except in the case of beekeeping. In the choice of breeds, the choice of characteristics that are important for organic agriculture, such as a high degree of genetic diversity, the capacity to adapt to local conditions and disease resistance, should be encouraged.
- (41) Organic animals are not always available in sufficient quantity and quality to meet the needs of farmers who wish to constitute a herd or a flock for the first time or to increase or renew their livestock. Under certain conditions, it should therefore be possible to bring non-organically raised animals to an organic production unit.
- (42) Livestock should be fed on feed materials produced in accordance with the rules of organic production, and preferably coming from the farmer's own holding, taking into account the physiological needs of the livestock. However, farmers should be given the possibility to use also in-conversion feed coming from their own holdings, under certain conditions. In addition, in order to provide for the basic nutritional requirements of livestock, farmers should be allowed to use certain feed material of microbial or of mineral origin or certain feed additives and processing aids under well-defined conditions.
- (43) Animal health management should mainly be based on the prevention of disease. In addition, specific cleaning and disinfection measures should be applied. The preventive use of chemically synthesised allopathic medicinal products, including antibiotics, should not be permitted in organic production. In the event of sickness or injury of an animal requiring immediate treatment, the use of such products should be limited to the minimum necessary to re-establish the well-being of the animal. In such cases, in order to guarantee the integrity of organic production for consumers, the official withdrawal period after use of such medicinal products as specified in the relevant Union legislation should be double the normal withdrawal period and have a minimum duration of 48 hours.
- (44) Organic livestock housing conditions and husbandry practices should satisfy the behavioural needs of the animals and should ensure a high level of animal welfare, certain aspects of which should go beyond the Union animal welfare standards applicable to livestock production in general. In most cases, livestock should have permanent access to open-air areas for exercise. Any suffering, pain or distress should be avoided, or should be kept to a minimum at all stages of the animals' lives. Tethering and mutilation, such as tail-docking for sheep, beak trimming in the first three days of life and disbudding, should only be possible if allowed by competent authorities, and only under certain conditions.
- (45) Since organic production is the most developed for bovine animals, ovine animals, caprine animals, equine animals, cervine animals and porcine animals, as well as for poultry, rabbits and bees, additional detailed production rules should apply to those species. For those species it is necessary for the Commission to lay down certain requirements that are important for the production of those animals, such as requirements for stocking density, minimum surfaces and characteristics, as well as technical requirements for housing. For other species, such requirements should be laid down once additional detailed production rules apply to those species.
- (46) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of the reduction of the derogations concerning the origin of animals, limits on organic nitrogen linked to the total stocking density, the feeding of bee colonies, acceptable treatments for the disinfection of apiaries, methods and treatments to fight against *Varroa destructor*, and detailed livestock production rules for further species.
- (47) This Regulation reflects the objectives of the new Common Fisheries Policy as regards aquaculture, which plays a key role in ensuring sustainable, long-term food security as well as growth and employment, while reducing pressure on wild fish stocks, in the context of growing global aquatic food demand. The communication of the Commission of 29 April 2013 on Strategic Guidelines for the sustainable development of EU aquaculture highlights the main challenges faced by aquaculture in the Union and its potential for growth. That communication identifies organic aquaculture as a particularly promising sector, and highlights the competitive advantages that derive from organic certification.

- (48) Organic aquaculture is a relatively new field of organic production as compared to organic agriculture, where long experience exists at the farm level. Given consumers' growing interest in organic aquaculture products, further growth in the rate of conversions of aquaculture units to organic production is likely. This will lead to increased experience, technical knowledge and development, with improvements in organic aquaculture that should be reflected in the production rules.
- (49) Organic aquaculture should be based on the rearing of young stock originating from organic production units. Organic aquaculture animals for breeding or on-growing purposes are not always available in sufficient quantity and quality to meet the needs of operators that produce aquaculture animals. Under certain conditions, it should be possible to bring wild caught or non-organic aquaculture animals to an organic production unit.
- (50) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of feed for aquaculture animals and the veterinary treatment of those animals, and in respect of detailed conditions for broodstock management, breeding and juvenile production.
- (51) Operators producing organic food or feed should follow appropriate procedures based on the systematic identification of critical processing steps, in order to ensure that processed products comply with the organic production rules. Processed organic products should be produced using processing methods which guarantee that the organic characteristics and qualities of the products are maintained through all stages of organic production.
- (52) Provisions concerning the composition of processed organic food and feed should be laid down. In particular, such food should be produced mainly from organic agricultural ingredients or from other ingredients falling within the scope of this Regulation that are organic, with the limited possibility of using certain non-organic agricultural ingredients specified in this Regulation. In addition, only certain products and substances authorised in accordance with this Regulation should be allowed for use in the production of processed organic food and feed.
- (53) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of precautionary and preventive measures to be taken by operators producing processed food or feed, in respect of the type and composition of products and substances that are allowed for use in processed food, as well as conditions under which they may be used, and in respect of the calculation of the percentage of agricultural ingredients, including the specification of the additives allowed for use in organic production that are considered as agricultural ingredients for the purpose of calculating the percentage that needs to be achieved in order to describe the product as organic in the sales description.
- (54) Organic wine should be subject to the relevant rules on processed organic food. However, since wine is a specific and important category of organic products, additional detailed production rules should be laid down specifically for organic wine. Organic wine should be produced entirely from organic raw material, and only certain products and substances authorised in accordance with this Regulation should be allowed to be added. The use of certain oenological practices, processes and treatments in the production of organic wine should be prohibited. Other practices, processes and treatments should be permitted under well-defined conditions.
- (55) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of specifying additional prohibited oenological practices, processes and treatments and in respect of amending the list of permitted oenological practices, processes and treatments.
- (56) Initially, yeast was not considered an agricultural ingredient under Regulation (EC) No 834/2007 and therefore it did not count for the agricultural composition of organic products. However, Commission Regulation (EC) No 889/2008 ⁽¹⁾ introduced the obligation to consider yeast and yeast products as agricultural ingredients for

⁽¹⁾ Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1).

the purposes of organic production from 31 December 2013. Accordingly, from 1 January 2021, only organically produced substrates should be used in the production of organic yeast for use as food and feed. In addition, only certain products and substances should be allowed for use in its production, confection and formulation.

- (57) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of additional detailed yeast production rules.
- (58) While this Regulation should harmonise the organic production rules in the Union for all products falling within its scope, and should lay down detailed production rules for different categories of products, it will only be possible at a later stage to adopt certain production rules, such as additional detailed production rules for further animal species or for products that do not fall within the categories for which detailed production rules have been laid down in this Regulation. In the absence of such production rules at Union level, Member States should still have the possibility to lay down national rules for their own national production, provided that those rules are not contrary to this Regulation. However, Member States should not apply those national rules to products produced or marketed in other Member States where those products comply with this Regulation. In the absence of such national detailed production rules, operators should at least comply with the general production rules and with the principles for organic production, insofar as those rules and principles could apply to the products concerned, when placing such products on the market with terms referring to organic production.
- (59) In order to take account of any future need to have specific production rules for products whose production does not fall within any of the categories of specific production rules laid down in this Regulation, as well as in order to ensure quality, traceability, compliance with this Regulation and, subsequently, adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of laying down detailed production rules, as well as rules on the obligation to convert, for such products.
- (60) Exceptions from organic production rules should be provided for only in the event of catastrophic circumstances. In order to allow organic production to continue or recommence in such cases, the power to adopt certain acts should be delegated to the Commission in respect of laying down the criteria to determine whether a situation qualifies as catastrophic circumstances as well as specific rules, including possible derogation from this Regulation, on how Member States are to deal with such catastrophic circumstances and on the necessary monitoring and reporting requirements in such cases.
- (61) Under certain conditions organic products, in-conversion products and non-organic products can be collected and transported simultaneously. In order to duly separate organic, in-conversion and non-organic products during their handling and to avoid any commingling, specific provisions should be laid down.
- (62) In order to ensure the integrity of organic production and adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of rules on packaging and transport of organic products.
- (63) The use in organic production of certain products or substances as active substances to be used in plant protection products falling within the scope of Regulation (EC) No 1107/2009, fertilisers, soil conditioners, nutrients, non-organic components of animal nutrition of various origin, feed additives, processing aids and products for cleaning and disinfection should be limited to the minimum and made subject to the specific conditions laid down in this Regulation. The same approach should be followed regarding the use of products and substances as food additives and processing aids and regarding the use of non-organic agricultural ingredients in the production of processed organic food. Therefore, any possible use of such products and substances in organic production in general, and in the production of processed organic food in particular, should be defined, subject to the principles laid down in this Regulation and to certain criteria.
- (64) 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, as well as to ensure adaptation to technical developments, the power to adopt certain acts should be delegated to the Commission in respect of additional criteria for the authorisation of products and substances for use in organic production in general, and in the production of processed organic food in particular, as well as criteria for the withdrawal of such authorisations.

- (65) In order to ensure access to agricultural ingredients, where such ingredients are not available in organic form in sufficient quantity for the production of processed organic food, Member States should also have the possibility to allow the use of non-organic agricultural ingredients under certain conditions and for a limited period.
- (66) In order to foster organic production and address the need for reliable data, information and data on the availability on the market for organic and in-conversion plant reproductive material, for organic animals and for organic aquaculture juveniles needs to be collected and disseminated to farmers and operators. For that purpose, Member States should ensure that regularly updated databases and systems with such information are established on their territories, and the Commission should make such information public.
- (67) In order to ensure compliance with the requirements for organic production and to ensure consumer trust in this production method, it is necessary that operators inform competent authorities, or, where appropriate, control authorities or control bodies, of cases of suspicion of non-compliance with this Regulation, which is substantiated or cannot be eliminated, concerning products they produce, prepare, import or receive from other operators. Such suspicion may, *inter alia*, arise due to the presence of a product or substance that is not authorised for use in the production of a product that is intended to be used or marketed as an organic or in-conversion product. Operators should inform competent authorities where they are in position to substantiate a suspicion of non-compliance or where they cannot eliminate such a suspicion. In such cases, the products concerned should not be placed on the market as organic or in-conversion products for as long as the suspicion cannot be eliminated. Operators should cooperate with the competent authorities, and, where appropriate, with the control authorities or control bodies, in identifying and verifying the reasons for such non-compliance.
- (68) In order to avoid the contamination of organic production with products or substances that have not been authorised by the Commission for use in organic production for certain purposes, operators should take proportionate and appropriate measures which are under their control to identify and avoid risks of such contamination. Such measures should be regularly reviewed and adjusted if necessary.
- (69) In order to ensure a harmonised approach across the Union as regards the measures to be taken in the case of suspicion of non-compliance, especially where such suspicion arises due to the presence of non-authorised products and substances in organic or in-conversion products, and to avoid uncertainties for operators, competent authorities, or, where appropriate, control authorities or control bodies, should carry out an official investigation in accordance with Regulation (EU) 2017/625 in order to verify compliance with the requirements for organic production. In the specific case of suspicion of non-compliance due to the presence of non-authorised products or substances, the investigation should determine the source and the cause of the presence of such products or substances, in order to ensure that operators comply with the requirements for organic production and, in particular, have not used products or substances that are not authorised for use in organic production, and to ensure that those operators have taken proportionate and appropriate precautionary measures to avoid the contamination of organic production with such products and substances. Such investigations should be proportionate to the suspected non-compliance, and therefore should be completed as soon as possible within a reasonable period, taking into account the durability of the product and the complexity of the case. They could include any method and technique for official controls which is considered appropriate to efficiently eliminate or confirm, without any unnecessary delay, any suspicion of non-compliance with this Regulation, including the use of any relevant information that would permit the elimination or confirmation of any suspicion of non-compliance without an on-the spot inspection.
- (70) The occurrence of the presence of products or substances that are not authorised for use in organic production in products that are marketed as organic or in-conversion products, as well as the measures taken in that respect, should be subject to further observation by Member States and the Commission. The Commission should therefore present a report to the European Parliament and the Council four years after the date of application of this Regulation, based on the information collected by Member States about the cases where non-authorised products and substances in organic production have been investigated. Such report could be accompanied, if appropriate, by a legislative proposal for further harmonisation.

- (71) In the absence of such further harmonisation, Member States that have developed approaches to avoid products that contain a certain level of products or substances not authorised for use in organic production for certain purposes being marketed as organic or in-conversion products should have the possibility to keep applying those approaches. However, in order to ensure the free movement of organic and in-conversion products in the internal market of the Union, such approaches should not prohibit, restrict or impede the placing of products produced in other Member States in compliance with this Regulation on the market. Such approaches should therefore only be applied to products produced on the territory of the Member State that has chosen to continue to apply that approach. Member States that decide to use this possibility should inform the Commission without delay.
- (72) In addition to the obligations concerning measures to be taken by operators producing, preparing, importing or using organic and in-conversion products and by competent authorities, or, where appropriate, by control authorities or control bodies, laid down in this Regulation in order to avoid the contamination of organic or in-conversion products with products or substances not authorised for use in organic production, Member States should also have the possibility of taking other appropriate measures on their territory to avoid the unintended presence of non-authorised products and substances in organic agriculture. Member States that decide to use this possibility should inform the Commission and other Member States without delay.
- (73) The labelling of agricultural products and foodstuffs should be subject to the general rules laid down in Regulation (EU) No 1169/2011 of the European Parliament and of the Council ⁽¹⁾, and in particular to the provisions aimed at preventing labelling that might confuse or mislead consumers. In addition, specific provisions relating to the labelling of organic and in-conversion products should be laid down in this Regulation. They should protect both the interests of operators in having their products correctly identified on the market and in enjoying conditions of fair competition, and the interests of consumers in being able to make informed choices.
- (74) Accordingly, the terms used to indicate organic products should be protected throughout the Union against their use in the labelling of non-organic products, independently of the language used. That protection should also apply to the usual derivatives or diminutives of those terms, whether they are used alone or combined.
- (75) Processed food should be labelled as organic only where all or almost all of the ingredients of agricultural origin are organic. To encourage the use of organic ingredients, it should also be possible to refer to organic production only in the list of ingredients of processed food where certain conditions are satisfied, in particular that the food in question complies with certain organic production rules. Special labelling provisions should also be laid down to allow operators to identify the organic ingredients that are used in products which consist mainly of an ingredient that stems from hunting or fishing.
- (76) Processed feed should be labelled as organic only where all or almost all the ingredients of agricultural origin are organic.
- (77) In order to create clarity for consumers throughout the Union market, the use of the organic production logo of the European Union should be obligatory for all organic prepacked food produced within the Union. In addition, it should be possible to use that logo on a voluntary basis in the case of non-prepacked organic products that are produced within the Union and in the case of any organic products imported from third countries, as well as for information and educational purposes. The model of the organic production logo of the European Union should be set out.
- (78) However, in order not to mislead consumers as to the organic nature of the entire product, it is appropriate to limit the use of that logo to products which contain only, or almost only, organic ingredients. It should therefore not be allowed to use it in the labelling of in-conversion products or processed products of which less than 95 % by weight of their ingredients of agricultural origin are organic.

⁽¹⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

- (79) To avoid any possible confusion among consumers about the Union or non-Union origin of a product, whenever the organic production logo of the European Union is used, consumers should be informed about the place where the agricultural raw materials of which the product is composed have been farmed. In that context, it should be allowed to refer to aquaculture in the label of products from organic aquaculture instead of referring to agriculture.
- (80) In order to provide clarity for consumers, and to ensure that the appropriate information is communicated to them, the power to adopt certain acts should be delegated to the Commission in respect of laying down additional rules on the labelling of organic products and amending the list of terms referring to organic production set out in this Regulation, the organic production logo of the European Union, and the rules relating thereto.
- (81) Certain products or substances used in plant protection products or as fertilisers should not fall within the scope of this Regulation and should therefore, in principle, not be subject to the rules of this Regulation, including the rules on labelling. However, since those products and substances play an important role in organic agriculture and their use in organic production is subject to authorisation under this Regulation, and since certain uncertainties as regards their labelling appeared in practice, in particular as regards the use of terms referring to organic production, it should be made clear that where such products or substances are authorised for use in organic production in accordance with this Regulation, they may be labelled accordingly.
- (82) Organic production is only credible if accompanied by effective verification and controls at all stages of production, processing and distribution.
- (83) Specific requirements for operators should be laid down to ensure compliance with this Regulation. In particular, provisions should be made for the notification of operator's activities to the competent authorities and for a certification system to identify the operators that comply with the rules governing organic production and the labelling of organic products. Those provisions should in principle also apply to any subcontractors of the operators concerned, unless the subcontracting activity is entirely integrated within the main activity of the subcontracting operator, and is controlled in that context. The transparency of the certification system should be ensured by requiring Member States to make public the lists of operators that have notified their activities, and any fees that may be collected in relation to the controls performed for the verification of compliance with the rules governing organic production.
- (84) Small retail shops not selling organic products other than prepacked organic products present a relatively low risk of non-compliance with organic production rules, and they should not face disproportionate burdens for selling organic products. They should therefore not be subject to the notification and certification obligations, but should remain subject to official controls performed for the verification of compliance with the rules governing organic production and the labelling of organic products. Equally, small retail shops selling unpacked organic products should be subject to official controls, but in order to facilitate the marketing of organic products, Member States should have the possibility of exempting such shops from the obligation to certify their activities.
- (85) Small farmers and operators that produce algae or aquaculture animals in the Union individually face relatively high inspection costs and administrative burdens linked to organic certification. A system of group certification should be allowed in order to reduce the inspection and certification costs and the associated administrative burdens, strengthen local networks, contribute to better market outlets and ensure a level playing field with operators in third countries. For that reason, the concept of 'group of operators' should be introduced and defined, and rules should be established that reflect the needs and resource capacity of small farmers and operators.
- (86) In order to ensure the effectiveness, efficiency and transparency of the organic production and of the labelling of organic products, the power to adopt certain acts should be delegated to the Commission in respect of the requirements for keeping records by operators or groups of operators and the model of the certificate of compliance.
- (87) In order to ensure that the certification of groups of operators is done effectively and efficiently, the power to adopt certain acts should be delegated to the Commission in respect of the responsibilities of the individual members of groups of operators, the criteria to determine the geographical proximity of their members, and the set-up and functioning of their systems for internal controls.