

Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 19,525, 22 ta' Jannar, 2016

Taqsimha B

L.N. 35 of 2016

**PRODUCT SAFETY ACT
(CAP. 427)**

**Organic Production and Labelling of Organic Products
Regulations, 2016**

IN exercise of the powers conferred by article 38 of the Product Safety Act, the Minister for Social Dialogue, Consumer Affairs and Civil Liberties, on the advice of the Director General (Technical Regulations), and in consultation with the Minister for Sustainable Development, the Environment and Climate Change, has made the following regulations:

1. (1) The title of these regulations is the Organic Production and Labelling of Organic Products Regulations, 2016. Citation and scope.

(2) These regulations implement the relevant provisions of Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 and Commission Regulation (EC) 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.

(3) These regulations shall concern the measures to be taken to control the organic production and labelling of agricultural products referred to in Article 1(2) of the Council Regulation.

2. (1) In these regulations, unless the context otherwise requires: Interpretation.

"Act" means the Product Safety Act; Cap. 427.

"Agricultural Directorate" means the Agricultural Directorate within the Ministry responsible for Agriculture;

"Commission Regulation" means Commission Regulation (EC) 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;

"Council Regulation" means Council Regulation (EC) No 834/

2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91;

"Director" means the Director of Agriculture and includes, to the extent of the authority given, any officer authorised by him, in writing, to act on his behalf for any of the purposes of these regulations;

"Malta" has the same meaning as assigned to it by article 124 of the Constitution of Malta;

"Minister" means the Minister responsible for Agriculture and includes, to the extent of the authority given, any officer authorised by him, in writing, to act on his behalf for any of the purposes of these regulations.

(2) Unless the context otherwise requires, words and expressions used in these regulations shall have the same meaning assigned to them in Article 2 of the Council Regulation and Article 2 of the Commission Regulation.

(3) In the event that any of these regulations conflict with the provisions of the Council Regulation or of the Commission Regulation, the provisions of the Council Regulation or of the Commission Regulation respectively shall prevail.

Designation of
the competent
authority.

3. (1) For the purposes of these regulations, the Council Regulation and the Commission Regulation, the Agricultural Directorate is hereby being designated as the competent authority.

(2) Without prejudice to the functions of the competent authority, as established by the Council Regulation and the Commission Regulation, the Agricultural Directorate shall:

(a) have the power to carry out official controls in the field of organic production in accordance with documented procedures;

(b) be responsible for the drawing up of reports on the controls it carries out;

(c) be responsible for the market surveillance of the selling and, or advertising of organic products;

(d) in cases where there is found to be a breach of these regulations, the Council Regulation or the Commission Regulation, take any measure it deems fit in order to ensure that said regulations are adhered to;

(e) have any other function necessary for the better implementation of the provisions of these regulations.

4. (1) The competent authority may confer, in whole or in part, its competence for the inspection and certification in the field or organic production in accordance with the provisions set out in these regulations, the Council Regulation and the Commission Regulation to one or more control authorities or control bodies:

Delegation of functions.

Provided that the competent authority shall publish, in the Gazette, a notice regarding such delegation.

(2) Whenever the competent authority appoints a control authority or control body to perform control tasks in terms of this regulation, it shall attribute a code number to each control authority.

(3) The control authorities and, or control bodies shall offer adequate guarantees of objectivity and impartiality and shall have at their disposal the qualified staff and resources necessary to carry out their functions.

(4) The competent authority shall be responsible for the delegation of control tasks to the control bodies and, or control authorities and shall also be responsible for their supervision.

(5) The competent authority may if it deems necessary to do so withdraw the delegation conferred:

Provided that the competent authority shall publish the withdrawal of delegation in the Gazette.

(6) Control authorities and, or control bodies appointed by the competent authority shall not have the authority to:

(a) perform supervision and audits of other control bodies; or

(b) grant exceptions to operators.

5. (1) Without prejudice to regulation 4 and without prejudice to the functions of the control authorities and, or control bodies as established by the Council Regulation and or the Commission Regulation, if authorised by the competent authority the control authorities and, or control bodies may be responsible for:

Function of the control authorities and, or control bodies.

(a) the verification of the operators' declaration in accordance with article 63 of the Commission Regulation and other general and specific documents as outlined in the Council

Regulation and the Commission Regulation;

(b) the taking of samples and carrying out of analysis in case of suspicion of non-authorised products and, or procedures;

(c) the drawing up of control reports, which reports are to be made available to the competent authority;

(d) the keeping of an updated list of names and addresses of operators under their control, which list should be made available to the competent authority;

(e) certifying all operators that comply with all national and EU legislation pertinent to the organic production and labelling of organic production and labelling and who also contribute to the control expenses and to provide documentary evidence to the operator in case he meets the organic requirements;

(f) in cases of non-compliance, prohibiting certified operators from placing, on the market, products indicating the organic status;

(g) maintaining effective and timely communication with the competent authority and provide the latter with information requested from it from time to time, both for reasons of supervision and compiling of reports to be sent to the European Commission.

(2) Every control authority and, or control body shall inform the competent authority of cases of infringement and, or irregularities which compromise the organic status of a product by not later than two working days from the discovery of such infringement and, or irregularity.

Organic
Farming
Advisory Board.

6. (1) There shall be a Board to be known as the Organic Farming Advisory Board, which shall consist of:

(a) the Director of the Agricultural Directorate *ex officio*, who shall act as Chairperson;

(b) two officers from the Agricultural Directorate, one of whom shall be appointed Deputy Chairperson;

(c) One member from every control authority and control body;

(d) a certified organic operator;

(e) two members from organisations directly involved in organic farming provided that they obtain approval by the Directorate to sit on the Board.

(2) The Director shall designate an officer from the Agricultural Directorate to act as Secretary to the Board.

(3) The Board shall:

(a) act in accordance with the terms of reference and rules of procedure as approved by the Director;

(b) set up special sub-committees or invite people as the Board may deem fit for the purpose of dealing with matters requiring specialised knowledge or experience.

(4) A person shall not be eligible to be appointed a member of the Board, or to continue to be a member of the Board, if such person:

(a) is a member of the House of Representatives; or

(b) is legally incapacitated; or

(c) has been declared bankrupt or has made a composition with his creditors; or

(d) has been convicted of:

(i) any crime affecting public trust; or

(ii) theft; or

(iii) fraud; or

(iv) knowingly receiving property obtained by theft or fraud; or

(v) any offence against the Act or any regulations made thereunder.

(5) The functions of the Board shall be:

(a) to advise the competent authority in the making of policies regulating the organic sector;

(b) to monitor and keep under review the proper implementation, functioning or attainment, to the highest

standards achievable, of the purpose of these regulations and of Government policy for the organic sector;

(c) to participate in ensuring the highest standard possible for Malta in the organic sector and to co-operate and co-ordinate as necessary with government departments and other bodies in the achievement of these aims;

(d) to provide the Minister and competent authority with technical and scientific advice in the field of organic production and related issues, as the Minister may from time to time request;

(e) to initiate and participate in research, surveys, programmes, and other activities as may be deemed necessary by the competent authority or by the Minister for the attainment of the optimum level of organic production and products, and control and to prepare and maintain the necessary resources and databases for carrying out this task; and

(f) to perform any other function or duties and to exercise such further powers or responsibilities as the Minister may from time to time determine.

(6) Subject to any rules which the Minister may prescribe, the Board shall regulate its own procedure.

(7) The Board shall meet when convened by the Chairperson, of his own motion or upon request by any member of the Board, or, in his absence, by the Deputy Chairperson, upon request by any member of the Board.

(8) The Board shall report to the competent authority and shall prepare and present to the competent authority and to the Minister an annual report containing the minutes of each Board meeting, a summary of the main outcomes of these meetings and put forward proposals as to organic production and labelling in Malta for the following year.

Control
officials.

7. (1) The competent authority may designate public officers to act as authorised officers for the control of the organic sector.

(2) No person who is engaged directly or indirectly in any commercial enterprise related to the production of organic-related products, shall act as an authorised officer, and no public officer shall be engaged directly or indirectly in any commercial enterprise related to the production and commercialisation of organic products.

(3) An authorised officer, designated in accordance with sub-regulation (1) -

(a) shall have the power, at any reasonable time, to enter and inspect any premises in or at which he has reason to believe that any organic product is being produced, processed, packed, stored, sold or offered for sale, to examine and search such premises, to inspect any such product and take samples;

(b) shall have the right to access and inspect documentation relating to any registers, records and notes kept in accordance with the provisions of these regulations; and

(c) may, exercising any power conferred by this regulation, seize and obtain any records which he has reason to believe may be required as evidence in proceedings under these regulations and in the case where the records are kept by means of a computer, require the records to be printed.

(4) Any authorised officer who discloses to any person any information obtained by him in the course of his duties with regards to any trade secret shall, without prejudice to any other liability under any other law, unless the disclosure is made necessary in the performance of his duty, be guilty of an offence.

(5) Any person who intentionally obstructs or causes the obstruction of any person acting in proper exercise of his functions under these regulations or, without reasonable cause, fails to give to any person, acting in the exercise of his functions under these regulations, any assistance or information which he may be required to give under these regulations or any other law, or gives false or misleading information, shall be guilty of an offence.

(6) Criminal action for such an offence shall be barred by the lapse of three months.

8. (1) No product shall be produced, processed, labelled, marketed or sold in Malta as being organic unless it conforms to the provisions of these regulations, the Council Regulation and the Commission Regulation. Certification.

(2) No operator shall produce, process, prepare, sell or market any product labelled as organic unless this operator has obtained the relevant certification from the competent authority, control authority or control body as indicated by the competent authority.

(3) Further to the provisions of sub-regulation (2), the competent authority shall establish the necessary procedures in order

for operators to be granted the certification referred to in sub-regulation (2); applicants shall refer to the competent authority to initiate the process of certification, and shall subsequently be guided on certification procedures by the competent authority.

(4) Each certificate issued shall be valid for a period of three years:

Provided that every certificate holder shall be subject to an inspection in order to ensure compliance with the provisions of these regulations, the Council Regulation and the Commission regulation at least once every year:

Provided further that the Agricultural Directorate shall, upon a report from a third party or on its own initiative, carry out on-the-spot inspections in order to verify that these regulations, the Council Regulation and the Commission Regulation are being adhered to:

Provided further that each control body and, or authority issuing the certificate shall carry out an inspection on each certified operator at least once a year.

Fees. **9.** The fee charged in order for the certificate to be issued shall be decided by the competent authority, the control authority or the control body, as the case may be, and published on the competent authority's website.

Authority to receive notifications. **10.** The authority responsible to receive notifications in terms of Article 28(3) of the Council Regulation shall be the Agricultural Directorate.

Period in which runs must be empty. **11.** For the purposes of Article 23(5) of the Commission Regulation, the period in which runs must be empty shall be of one month.

Authorisation of non-organic food ingredients of agricultural origin. **12.** The authorisation referred to in Article 29(1)(b) of the Commission Regulation may be prolonged for a maximum of three times of twelve months each.

Conversion. **13.** The conversion period referred to in Article 36(4) of the Commission Regulation shall be shortened to a period of not less than one year:

Provided that this regulation shall only apply following these two cases:

(a) parcels treated with a product not authorised for

organic production as part of a compulsory disease or pest control measure imposed by the competent authority of a Member State;

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

14. (1) The use of seed or vegetative propagating material not obtained by organic methods shall only be authorised if not available by organic methods.

Competent authority responsible for granting authorisation for the use of seed or vegetative propagating material not obtained by organic methods.

Provided that the provisions of Article 45(2) to (9) of the Commission Regulation shall apply for the authorisation for the use of seed or vegetative propagating material not obtained by organic methods.

(2) The competent authority shall, in accordance with article 45(4) of the Commission Regulation, be the authority responsible for granting authorisation referred to in Article 45(1)(b) of the Commission Regulation.

(3) The Plant Health Directorate shall, in accordance with article 54 of the Commission Regulation, send to the competent authority an annual report covering all authorisations from the previous calendar year and this by the end of February of each year.

15. (1) The Plant Health Directorate shall be responsible for establishing, managing and updating of a computerised database for the listing of the varieties for which seed or seed potatoes obtained by organic production methods are available in Malta.

Database.

(2) Registration of the varieties of seed or seed potatoes produced by organic methods shall follow the provisions laid down in Articles 49 and 50 of the Commission Regulation.

(3) Any seed variety which has not been registered in the database shall be considered as unavailable and may not be used by organic operators in Malta.

(4) The database shall be updated for each species or group of species cultivated in Malta, every three months.

(5) The manager of the database may, with the approval of the competent authority, refuse a supplier's application for registration or delete a previously accepted registration if the supplier does not comply with the requirements set out in these regulation, the Council Regulation or the Commission Regulation.

(6) For each registered variety the information provided shall at least include that contained in Article 51 of the Commission Regulation.

(7) Each registration shall be subject to a fee, which represents the cost of inserting and maintaining the information in the database:

Provided that the fee shall be approved by the competent authority and published in the Gazette.

Access to
information.

16. (1) The information contained in the database shall be available online and free of charge to the users of seed or seed potatoes and also to the public:

Provided further the seed database manager shall, every December, notify to the users who have notified their activity in accordance with Article 28(1)(a) of the Council Commission Regulation, the procedures in place for extracting information from the seed database.

Exemptions and
derogations.

17. (1) Pursuant to Article 28(2) of the Council Commission Regulation, operators who sell products directly to the final consumer or user, provided that they do not produce, prepare, store other than in connection with the point of sale or import such products or have contracted out such activities to a third party, shall be exempted from adherence to the control system as established by virtue of these regulations.

(2) The competent authority shall decide whether an operator falls within the parameters of sub-regulation (1) or not:

Provided that an operator shall be deemed to be exempted only if he is declared as such in writing by the competent authority.

Imports of
organic products
from third
countries.

18. Operators importing organic products from third countries shall adhere to the requirements and procedures laid down by the Agricultural Directorate.

Measures in
case of
irregularities
and
infringement.

19. (1) Where an irregularity is found as regards compliance with the requirements laid down in these regulations, the Council Regulation or the Commission Regulation, the competent authority, the control authority and, or the control body, as the case may be, shall order that no reference to the organic production method is made in the labelling and advertising of the entire lot or production run affected by this irregularity:

Provided that this would be proportionate to the relevance of the requirement that has been violated and to the nature and

particular circumstances of the irregular activity.

(2) Where a severe infringement or an infringement with prolonged effect is found, the competent authority, control authority or control body shall prohibit the operator concerned from marketing products which refer to the organic production method in the labelling and advertising for a period to be agreed with the competent authority.

(3) (a) An infringement shall fall under the classification of a severe infringement if that infringement compromises the organic status of the product, that is it directly goes against the basic principles of the organic production method as defined in the Council Regulation and its Implementing Acts. In cases of irregularities a warning letter shall be sent by the competent authority setting out the conditions required to rectify the operators' position, if such operators do not comply with these conditions the irregularity shall also be considered as a severe infringement.

(b) An infringement with prolonged effect is an infringement where the action done by an operator does not only compromise the organic status of the existent product but also that of future products.

(4) The competent authority, control body or control authority may suspend or withdraw an operator's participation in the Organic certification scheme if it results that the operator has failed to adhere to the conditions related to the participation in the scheme:

Provided that the competent authority, control body or control authority may if deemed necessary, prior to suspending or withdrawing an operator's participation in the scheme, issue a warning notifying the operator of the infringement and the obligation to take remedial action.

If an operator's Organic Status or In-conversion Status is withdrawn, that operator may not apply for the Organic Certification for three years from the date of withdrawal.

20. In addition to the provisions laid down in regulation 19, ^{Penalties.} any person who commits a severe infringement shall be guilty of an offence and shall be liable:

(a) on a first conviction to a fine (*multa*) of not less than five hundred euro (€500) but not exceeding one thousand five hundred euro (€1,500);

(b) on a second conviction or subsequent conviction,

to a fine (*multa*) of not less than one thousand five hundred euro (€1,500) but not exceeding two thousand and five hundred euro (€2,500) or to a fine calculated on the profit made by the offender in connection with the transaction in contravention to these regulations, whichever is the higher:

Provided that, when the fine is so calculated, it may not exceed five times the profit made by the offender:

Provided further that the Court may, in addition to any other punishment, sentence the offender to imprisonment for a term of not less than thirty days and not exceeding two years:

Provided further the Court shall, on the demand of the prosecution, order the forfeiture of any goods to which the offence relates:

Provided further the Court shall, on demand of the prosecution, in the case of a second or subsequent conviction, order the suspension of the offender's certification for a period of not less than one week and not more than three months, or the cancellation of any licence or permit held by the offender and relating to any trade or business to which the offence relates, and shall order that any such cancelled licence or permit may not be re-issued in respect of the convicted offender.

Revocation of
the Organic
Farming
Regulations,
2004.
L.N. 237 of
2004.

21. The Organic Farming Regulations, 2004, are hereby revoked without prejudice to anything done or omitted to be done thereunder.

