

Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 19,934, 12 ta' Jannar, 2018

Taqsima B

L.N. 15 of 2018

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

**Organic Production and Labelling of Organic
Products Regulations, 2018**

IN exercise of the powers conferred by article 38 of the Product Safety Act, the Minister for Justice, Culture and Local Government on the advice of the Director General (Technical Regulations), and in consultation with the Minister for the Environment, Sustainable Development 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, 2018. Citation and scope.

(2) These regulations provide for the implementation of the provisions of:

(a) 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 any amendments thereto, hereinafter referred to as "Council Regulation"; and

(b) 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, as may be amended from time to time, hereinafter referred to as "Regulation (EC) 889/2008"; and

(c) Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down rules for the implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries, and any amendments thereto, hereinafter referred to as "Regulation (EC) 1235/2008".

(3) These regulations 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. Cap. 427.

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

"Act" means the Product Safety Act;

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

"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;

"infringement with a prolonged effect" means an infringement where the action done by an operator does not only compromise the organic status of the existing product but also that of future products;

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

"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;

"organic production" has the same meaning as in Article 2(a) of the Council Regulation;

"severe infringement" means an infringement that compromises the organic status of the product, that is, it directly goes against the basic principles of the organic production method.

(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, Article 2 of the Regulation (EC) 889/2008, and Article 2 of Regulation (EC) 1235/2008.

(3) In the event that any of these regulations conflict with the provisions of the Council Regulation, Regulation (EC) 889/2008, or Regulation (EC) 1235/2008, the provisions of the latter shall prevail.

Designation of
the competent
authority.

3. (1) For the purposes of these regulations, the Council Regulation, Regulation (EC) 889/2008, and Regulation (EC) 1235/2008 the 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, Regulation (EC) 889/2008, and Regulation (EC) 1235/2008, the 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 drawing up of reports on the

controls it carries out;

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

(d) in cases where there is a breach of these regulations, the Council Regulation, Regulation (EC) 889/2008, or Regulation (EC) 1235/2008, take any measure it deems fit in order to ensure that the said regulations are adhered to;

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

(3) The Director may issue guidelines regarding compliance with the provisions of these regulations which directly or indirectly regulate the organic sector:

Provided that these guidelines shall be published in the Gazette and shall be read in conjunction with these regulations and shall be legally binding.

4. (1) The competent authority may confer in whole or in part, its competence for the inspection and certification in the field of organic production in accordance with the provisions set out in these regulations, the Council Regulation, Regulation (EC) 889/2008, and Regulation (EC) 1235/2008 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 conferral of 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 its 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 as defined in Article 92c of Regulation (EC) 889/2008.

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

Provided that such withdrawal of delegation shall be published in the Gazette.

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(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.

Function of the control authorities and, or control bodies.

5. (1) Without prejudice to regulation 4 and to the functions of the control authorities and, or control bodies as established by the Council Regulation, Regulation (EC) 889/2008, and Regulation (EC) 1235/2008, if authorised by the competent authority the control authorities and, or control bodies shall be responsible for the:

- (a) verification of the operators' declaration in accordance with Article 63 of Regulation (EC) 889/2008 and other general and specific documents as outlined in the Council Regulation, Regulation (EC) 889/2008, and Regulation (EC) 1235/2008;

- (b) taking and analysing of samples for the detection of products not authorised for organic production, and for checking production techniques not in conformity with the organic production rules;

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

- (d) keeping of an updated list of names and addresses of operators under their control, which list should be made available to interested parties;

- (e) certifying all operators that comply with all national and EU legislation pertinent to the organic production and labelling of organic products and to provide documentary evidence to the operators in case they meet the organic requirements, as referred to in Article 29 of the Council Regulation;

- (f) in cases of non-compliance, prohibiting certified operators from placing on the market products indicating the organic status, and any other necessary action as listed in the catalogue of measures referred to in Article 92d of Regulation (EC) 889/2008;

- (g) maintaining effective and timely communication with the competent authority and providing the latter any relevant information as may be requested from time to time, both for reasons of supervision and for reporting purposes.

(2) Every control authority and, or control body shall inform the competent authority of cases of infringements 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.

6. (1) There shall be established an Organic Farming Advisory Board, as appointed by the Minister, which shall consist of: Organic Farming Advisory Board.

- (a) the Director *ex officio*, who shall act as Chairperson;
- (b) two officers from the Directorate, one of whom shall be appointed Deputy Chairman;
- (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.

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

(3) The Board shall:

- (a) regulate its own procedure as it deems fit;
- (b) set up special sub-committees or invite technical experts 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 as 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 Minister on any matters with which

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these regulations are concerned and the formulation of policies in this regard;

(b) to monitor and regularly review the implementation, functioning or attainment, to the highest standards achievable, of the provisions and policies relevant to the organic sector;

(c) to ensure a high standard in the organic sector by addressing pertinent matters arising from the application of these regulations;

(d) to provide 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 Minister, for the attainment of the optimum level of organic production and products;

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

(6) 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.

(7) The Board shall prepare and present to the Minister by the 31st December of each year, 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.

Authorised
officers.

7. (1) The Director may designate public officers to act as authorised officers for the control of these regulations.

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

(3) An authorised officer may:

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

(b) stop and, or board any vehicle or vessel that the officer has reasonable grounds to believe is transporting organic products;

(c) inspect the premises, any plant, machinery or

equipment, containers and organic products found on the premises;

(d) have access to, examine and copy any documentation, records, registers or other information to which these regulations may apply, in whatever form they are held, and remove them to enable them to be copied or require computer records to be produced in a form in which they may be easily accessed and taken away by the officer;

(e) take samples of any product in relation to these regulations and carry out any examination, investigation or test; and

(f) take photographs, measurements, or recordings.

8. (1) No product shall be produced, processed, labelled, marketed or sold in Malta as being organic unless it conforms with the provisions of these regulations, the Council Regulation, Regulation (EC) 889/2008, and Regulation (EC) 1235/2008. 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) The competent authority shall establish the necessary procedures in order for operators to be granted the certification referred to in sub-regulation (2). Applicants must refer to the competent authority to initiate the process of certification, and shall subsequently be guided on certification procedures.

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

Provided that every certificate holder shall be subject to at least an annual inspection in order to ensure compliance with the provisions of these regulations, the Council Regulation, Regulation (EC) 889/2008, and Regulation (EC) 1235/2008 once every year:

Provided further that the Directorate shall, upon a report from a third party or on its own initiative carry out inspections in order to verify that these regulations are being adhered to.

(5) The fee to be charged to operators submitting their undertaking to the control system shall be decided by the competent authority, the control authority or the control body as the case may be, and published on the website of the relevant authority.

(6) No operator shall change the control authority or control body, under which he has been granted certification, until any pending

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irregularities have been resolved through the necessary measures.

Authority to
receive
notifications.

9. The authority responsible to receive notifications in terms of article 28 of the Council Regulation shall be the Directorate.

Period in which
poultry runs
must be empty.

10. For the purposes of Article 23(5) of Regulation (EC) 889/2008, the period in which poultry runs must be empty shall be that of one month.

Authorisation of
non-organic
food ingredients
of agricultural
origin.

11. The provisional authorisation period referred to in Article 29 (1)(b) of Regulation (EC) 889/2008 may be renewed for a maximum of three times of 12 months each, by the competent authority as the case may be.

Conversion.

12. The conversion period referred to in Article 36(4) of Regulation (EC) 889/2008 may be shortened to a period of not less than one year, depending on the case concerned:

Provided that this regulation shall only apply in the following 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;

(b) parcels treated with a product not authorised for organic production as part of scientific pests approved by the competent authority:

Provided further that that harvest following the treatment may not be sold with reference to the organic production methods.

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

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

Provided that the provisions of Article 45, sub-paragraphs (2) to (9) of Regulation (EC) 889/2008 shall apply.

(2) The competent authority shall, in accordance with Article 45(4) of Regulation (EC) 889/2008, be the authority responsible for granting authorisations referred to in Article 45(1)(b) of Regulation (EC) 889/2008.

Seed database.

14. (1) For the purposes of Article 48 of Regulation (EC) 889/2008, the directorate responsible for plant protection 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 the organic production methods are available in Malta.

(2) Registration of the varieties of seed or seed potatoes produced by the organic production methods shall follow the

provisions laid down in Article 49(1) and Article 50(1) of Regulation (EC) 889/2008.

(3) Any seed variety which has not been registered in the database shall be considered as unavailable and shall 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 Regulation (EC) 889/2008.

(6) For each registered variety, the information provided shall at least include the information set out in Article 51 of Regulation (EC) 889/2008.

(7) A supplier shall be charged a fee for registering information in the database:

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

(8) The information in the database shall be made available online and free of charge, to the users of seed or seed potatoes and to the public:

Provided that the seed database manager shall every December notify the users referred to in this sub-regulation, the procedures in place for extracting the information.

15. (1) Pursuant to Article 28(2) of the Council 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, may be exempted from adherence to the control system as established by virtue of these regulations.

Exemption from requirement to adhere to the control system.

(2) The competent authority may define parameters to determine which type of operators may avail of the exemption provided for in sub-regulation (1):

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

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Imports of
organic products
from third
countries.

16. Operators importing organic products from third countries shall adhere to the requirements and procedures laid down in these regulations and in Regulation (EC) 1235/2008 or as may be defined by the competent authority from time to time.

Measures in
case of
irregularities
and
infringements.

17. (1) Where an irregularity is found as regards to compliance with the requirements laid down in these regulations, the Council Regulation, Regulation (EC) 889/2008, or Regulation (EC) 1235/2008, the competent authority, the control authority and/or the control body as the case may be, shall order in writing that no reference to the organic production method is made in the labelling, advertising, and retail 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.

Warning notice.

18. (1) In cases whereby the competent authority, control authority or control body consider the irregularity not to be of a severe nature, a warning notice shall be sent by the competent authority, control authority or control body, as the case may be, setting out the conditions required to rectify the operator's position and shall include the information specified in regulation 19(2)(a) to (d) of these regulations. If such operator does not comply with such conditions, the irregularity shall be considered as a severe infringement and the provisions established in regulation 19 shall apply.

(2) Where the competent authority, control authority and, or control body has reasonable cause to believe that any person has contravened or failed to comply with any of these regulations, whereby a severe infringement, or an infringement with a prolonged effect has been carried out, the competent authority, control authority and, or control body shall prohibit the operator concerned from marketing products which refer to the organic production method in the labelling, advertising and retail, for a period to be agreed with the competent authority and the provisions established in regulation 19 shall apply.

Enforcement
notice.

19. (1) Where any person fails to comply with a warning notice served in accordance with regulation 18(1) within the time specified therein, or in cases of a severe nature as referred to in regulation 18(2), the Director may issue an enforcement notice in accordance with sub-regulation (2) to be served on that person:

(2) An enforcement notice served terms of sub-regulation (1) shall specify:

- (a) the date and nature of the offence;
- (b) the facts upon which the allegation that an offence has been committed is based;
- (c) the measures that, in the Director's opinion, must be taken in order to ensure compliance;
- (d) the period within which any such measures must be taken, as is reasonable in the circumstances;

Provided that in addition to the enforcement notice, the competent authority, control authority, or control body may prohibit through a suspension, any certified operator from marketing products which refer to the organic production method in the labelling, advertising and retail, for a period to be agreed with the competent authority.

(3) Any enforcement notice sent by the Director shall be deemed to have been delivered and duly notified if it is physically delivered or sent by registered top post to the person at this place of residence or business or place of work or postal address of such person.

20. (1) Where any person fails to comply with an enforcement notice served in accordance to regulation 19 within the time specified therein, the Director may cause a notice in writing in accordance with sub-regulation (2) to be served on that person. Administrative penalties.

- (2) A notice under sub-regulation (1) shall specify:
 - (a) the date and nature of the offence;
 - (b) a summary of the facts upon which the allegation that an offence has been committed is based (being a sufficient summary fully and fairly to inform the person of the allegation against him);
 - (c) any other matter (not being previous convictions) that the Director considers relevant to the imposition of a penalty;
 - (d) the amount of the penalty due and, where the penalty due depends on a previous conviction, the date of such conviction, and shall be endorsed on a statement setting out the provisions of this regulation:

Provided that in addition to the notice of administrative penalties, in case of certified operators having an organic status or in-conversion status, the competent authority, control authority, or control body may withdraw such certification and organic status, and if so withdrawn it shall be for a period of three years from the date of withdrawal.

(3) Any person on whom a notice under sub-regulation (1) is served may, within thirty days after such service, by notice in writing served on the Director, require that proceedings in respect of the alleged offence shall be dealt with by the Court, in which case the following provisions shall apply:

(a) no further proceedings shall be taken under this regulation by the Director; and

(b) nothing in this regulation shall be construed as preventing the institution of any proceedings in respect of the alleged offence or the conviction of the person for the offence by the Court or the imposition of any penalty or forfeiture under these regulations upon such conviction.

(4) Any person on whom a notice under sub-regulation (1) is served who does not wish that proceedings in respect of the alleged offence be dealt with by the Court may, within thirty days after such service, by notice in writing served on the Director:

(a) admit the offence;

(b) pay the amount of the penalty to the Director within thirty days after the penalty notice is served or after such subsequent period as the Director may determine; and

(c) where applicable take any necessary remedial actions to ensure conformity with these regulations.

(5) Where under this regulation a person admits an offence, the Director shall impose a monetary penalty on that person in respect of the offence amounting to one third of the maximum penalty to which the person would be liable if he were convicted of the offence by the Court.

(6) The penalty imposed under sub-regulation (5) shall be due as civil debt enforceable by the competent Court of civil jurisdiction in favour of the Government and the declaration by the person on whom the penalty is imposed that he admits the charge shall constitute an executive title for the purposes of article 253 of the Code of Organization and Civil Procedure in the same manner as if it were a judgement of the competent Court of civil jurisdiction.

(7) Notwithstanding any other provision of these regulations or of any other enactment, where an offence has been admitted under this article no charge may be laid in respect of the offence against any person by whom it has been admitted.

(8) Where a person on whom a notice under sub-regulation(1) is served does not, within thirty days after the notice is served on him,

admit the offence, the Director shall institute proceedings or cause proceedings to be instituted before the Court in respect of the alleged offence.

21. (1) Any person shall be guilty of an offence under these regulations if he: Offences and penalties.

(a) fails to comply with, or contravenes, or fails to comply with any order lawfully given in terms of, any of the provisions of these regulations, the Council Regulation, Regulation (EC) 889/2008, or Regulation (EC) 1235/2008;

(b) intentionally obstructs or causes the obstruction of any person acting in the proper exercise of his functions under these regulations and, or fails to allow an inspection authorised under these regulations;

(c) 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;

(d) conspires or attempts, or aids, or abets, any other person by whatever means, including advertising, counselling or procurement to contravene the provisions of these regulations or to fail to comply with any such provisions, including any order lawfully given in terms of any of the provisions of these regulations, or to contravene any restriction, prohibition or requirement imposed by or under the said regulations;

(e) alters, forges, counterfeits or destroys any document presented to or issued by the Director under these regulations;

(f) in case of an authorised officer, 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.

(2) Any person who is found guilty of an offence against the provisions of these regulations shall, on conviction, 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.

(3) Where any person is convicted of an offence against these regulations, the Court may, in addition to any other penalty that it may impose:

(a) sentence the offender to imprisonment for a term of not less than thirty days and not exceeding two years;

(b) order the forfeiture to the Government of any goods to which the offence relates, and if so forfeited shall be disposed of in such a manner as the Court may determine on the advice of the Director;

(c) order the suspension or withdrawal as the Court may deem proper, of the offender's certification, for a period not being less than one month and not more than three years, or the suspension of any licence or permit held by the offender and related to any trade or business to which the offence relates, and may in addition order that any such licence or permit may not be re-issued in respect of the convicted offender.

Onus of proof.

22. In any proceedings for an offence under these regulations consisting of a failure to comply with these regulations, the Council Regulation, Regulation (EC) 889/2008, or Regulation (EC) 1235/2008, it shall be for the accused to prove (as the case may be) that all the necessary precautions and due diligence were in fact done to satisfy the duty or requirement.

Repeal and
saving.
S.L. 427.54.

23. (1) The Organic Production and Labelling of Organic Products Regulations, are hereby repealed and replaced by these regulations, and any references in any law to the repealed Regulations, shall be construed as references to these regulations:

Provided that any orders and measures taken by virtue of the repealed Regulations shall remain in force as if made under these regulations.

(2) Legal Notice 1 of 2018 is hereby repealed.