IN EXERCISE of the powers conferred by article 10 of the Veterinary Services Act, the Minister responsible for veterinary services, after consultation with the Minister responsible for public health, has made the following rules:-

1. (1) The title of these rules is the Production and Sale of Dairy and Traditional Dairy Products Rules, 2022.

(2) The scope of these rules is to implement national measures, in line with Article 10 of Council Regulation (EC) No 853 of 2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, with respect to the production and sale of dairy and traditional dairy products manufactured in establishments in Malta.

(3) These rules shall come into force within two (2) months from their publication in the Gazette.

the objectives of such rules.

3. (1) In these rules, unless the context otherwise requires:

"Act" means the Veterinary Services Act;

"Commission" means the Food Safety Commission established by the Food Safety Act;


"Department" means the Department responsible for Veterinary Services;

"Director" means the Director responsible for Veterinary Services or any authorised officer duly appointed by him;

"EEA Agreement" means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992, as adjusted by the Protocol signed at Brussels on 17th March 1993 and as subsequently amended;

"EFTA Member States" means states which are members of the European Free trade Association;

"farm" means an establishment where one or more farmed animals are kept to produce milk which shall also include related premises;

"Farmers’ Market" means a market established in terms of regulation 3 of the Farmers’ Markets Regulations;

"Malta" shall have the same meaning as assigned to it in article 124 of the Constitution of Malta;

"open-air market" means any one of the markets listed in the Third Schedule to the Trading Licences Regulations or any market established in terms of the Farmers’ Market Regulations;

"qaleb" means a small traditional cheese basket where the traditional dairy product is placed;
"qanniċ" means traditional fabric used for air-drying the traditional dairy product;

"raw cream" means the cream obtained from the fat skimmed off raw milk;


"related premises" means premises belonging to the owner of the animals of a farm or premises which are being leased from another person for the purposes of these rules, which is not necessarily within the perimeter of the farm, but which is used for the processing of dairy and traditional dairy products from milk;

"sale from the farm" means sale directly to the final consumer at the same farm or from related premises;

"traditional dairy product" means a product made out of milk originating from sheep, goats or cows as follows:

(a) listed in the National Register of Traditional agro-food products of Malta in accordance with the Establishment of the National Register of Traditional Agro-Food Products of Malta Regulations; or

(b) registered in terms of Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs; or

(c) lawfully marketed in a Member State of the EU or in Turkey, or which is originating and lawfully marketed
in an EFTA Member State that is a contracting party to the EEA Agreement.

(2) Unless the context otherwise requires, words and phrases used in these rules which are not defined herein shall have the same meaning assigned to them in the Act and, or Council Regulation (EC) No 852/2004 and, or Council Regulation (EC) No 853/2004 and, or Regulation (EU) 2017/625 and, or Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

4. (1) No person shall sell dairy or traditional dairy products unless produced and labelled as required and in accordance with these rules.

(2) The placing on the market in Malta of raw milk or raw cream intended for direct human consumption shall be prohibited.

5. (1) All producers of dairy products and traditional dairy products shall be approved by the Department and registered with the Commission.

(2) Farms and, or related premises producing milk shall be registered with the Department.

(3) Without prejudice to provisions made under the Act with regards to the identification and registration of animals and Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health, all male and female animals of the species producing milk on the farm shall be identified and registered on the farm register and with the Department in accordance with the provisions of the respective laws and regulations.

(4) The animals referred to in sub-rule (3) shall be tested regularly for any diseases which may be identified as stipulated in Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health, as well as for any other disease as may be determined by the Director from time to time.

(5) The procedure for effecting a registration of a farm and animals in terms of this rule shall be determined by the Department.
6. The production of dairy products and traditional dairy products shall not be placed on the market, be sold in wholesale or retail or directly to the final consumer from the farm or from any related premises or from any other place unless these products originate from establishments as described in rule 5.

7. Dairy products or traditional dairy products may be produced on a farm or in a related premises outside the rules set by Council Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 and Council Regulation (EC) No 853/2004 and the provisions of these rules, if they are going to be consumed by the owner of the animals or his direct family living in the same household as the owner of the animals. Such a production shall only take place under these conditions on a farm or related premises where there are no more than seven (7) sheep or goats registered therein:

Provided that all the dairy or traditional dairy products produced on a farm or in a related premises where there are no more than seven (7) sheep or goats registered therein may be sold through sale from the farm and, or from an open-air market if the farm holding and related premises are registered in terms of Council Regulation (EC) No 852/2004 and they fulfil the requirements established therein.

8. Any person placing traditional dairy products on the market in Malta in accordance with these rules shall also abide by the measures set out in the Schedule and any other guidelines as may be issued by the Commission, from time to time, and published in the Gazette.

9. (1) Any person transporting or storing dairy products and, or traditional dairy products for wholesale shall be registered with the Department and the Commission in accordance with the Registration of Food Premises Regulations.

(2) Any person transporting or storing dairy products or traditional dairy products for retail shall be registered with the Department and the Commission in accordance with the Registration of Food Premises Regulations.

10. (1) Any person who contravenes or fails to comply with any of the provisions of these rules shall be guilty of an offence and shall, on conviction, be liable to the punishments contemplated in articles 35(2), 36(2), 37(2) and 38(2) of the Act which punishment may include imprisonment of not more than six (6) months or a fine (multa) of not less than four thousand euro (€4,000) and not more than twenty-three thousand and two hundred and ninety-three euro and seventy-three cents (€23,293.73) or both such imprisonment and fine
Where the Director has reasonable cause to believe that an offence against these rules has been committed by any person and, having regard to the previous conduct of the person concerned, it would be appropriate to impose an administrative penalty, the Director may decide to impose an administrative penalty in accordance with article 61 of the Act.

In accordance with the provisions of article 57(2) of the Act, where any person is convicted of an offence against these rules, the Court may, in addition to any other punishment that it may impose, order that those animals, instruments, appliances, products or substances used in the commission of the offence shall be forfeited in favour of the Government and, if so forfeited, shall be disposed of in such a manner as the Court may determine on the advice of the Director.

In the event of a second or subsequent conviction against these rules, the provisions of article 60 of the Act shall apply.

Without prejudice to the provisions of sub-rules (1) to (4) and to any provision of the Criminal Code which may apply in this regard, any person committing a breach of rules 5, 8 and 9 shall be subject to the provisions of articles 43 and 44 of the Food Safety Act which shall also apply in this regard together with any other punishments that may be imposed.

The provisions of sub-rules (1) to (4) shall continue to apply without prejudice to any pending criminal proceedings which shall have been instituted against the offender committing an offence against these rules.

In respect of actions and procedures for offences in connection with these rules, the Court may award in favour of the Government such costs and expenses incurred in relation to those actions and procedures as it may deem fit:

Provided that where the Director deems it more appropriate to impose an administrative penalty as stipulated under article 61 of the Act, the offender shall also pay for any costs or expenses incurred in relation to actions and procedures carried out during the inspection where irregularities are found.
SCHEDULE
Adoption of national measures

In terms of Article 10 of Council Regulation (EC) No 853/2004, the following national measures adopt Annex III of the said Regulation, as follows:

In the case of sheep and goat milk used for the production of traditional dairy products:

(a) the checks referred to in Council Regulation (EC) No 853/2004 in Annex III, Section IX, Chapter I, Part III, paragraph 2 shall be carried out before raw milk is to be used for production;

(b) the number of micro-organisms as referred to in Council Regulation (EC) No 853/2004 in Annex III, Section IX, Chapter I, Part III, paragraph 3 shall be set on the basis of the result of a test on an individual sample of raw milk twice a month;

(c) in line with Annex III, Section IX, Chapter I, Part IIB, paragraph 4 (b) and Annex III, Section IX, Chapter II, Part I, paragraph 2(b) of Council Regulation (EC) No 853/2004, the Director authorises the use of raw milk at a temperature of not less than 37°C within two (2) hours from milking for the production of traditional dairy products;

(d) in order to accommodate food business operators in terms of Article 10, paragraph 4 of Council Regulation (EC) No 853/2004, it shall be permissible to utilise raw milk originating from sheep and goats which:

   (i) do not show clinical signs of brucellosis (*B. melitensis*);

   (ii) having been tested for brucellosis (*B. melitensis*) using one of the tests listed in the Annex to Council Decision (EC) 90/242/EEC of 21 May 1990 introducing a Community financial measure for the eradication of brucellosis in sheep and goats at least once every twelve (12) months, where this test results negative;

   (iii) have been tested for any other disease in accordance with regulation 5(4) with negative results for any disease at least once every twelve (12) months;

   (iv) belong to a registered farm officially free or free
of brucellosis as stipulated under Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health;

(e) in order to enable the continued use of traditional methods for the production of traditional dairy products in terms of Article 10, paragraph 4, of Council Regulation (EC) No 853/2004, it shall be permissible:

(i) that the sheep and goats are hand milked as long as this milking takes place in an area which is not the area where these animals are kept and bred on the farm;

(ii) that the milk is filtered through a sieve preferably of food grade plastic or stainless steel and through a clean muslin cloth that is washed and boiled;

(iii) that the milk is placed in a food grade plastic or stainless steel container and is not cooled if it is going to be used for the production of traditional dairy products within two (2) hours of milking;

(iv) that this container with milk may be transported without being cooled as long as the trip between the place where the milking takes place and the place where the production of the traditional dairy products takes place does not take longer than sixty (60) minutes;

(v) as soon as this milk arrives at the place where the production of traditional dairy products takes place, this milk is transferred into a clay, stainless steel, aluminium or any other food grade material pot and is heated to 37°C;

(vi) that this temperature may be measured with thermometers that are appropriate for food preparation procedures;

(vii) as soon as the temperature is adequate, ‘qtar tat-tames’ or any form of other enzyme that induces milk to coagulate shall be added in accordance with the recipe described for the production of traditional dairy product;

(viii) the curd that forms shall be left to stand for thirty (30) minutes in an ambient temperature covered by a small meshed net;

(ix) that after such time the curd is lifted with a
skimmer and placed in a form (*qaleb*) made of food grade plastic or cane or reed;

(x) that this curd is pressed also by hand to make sure that the form is packed well and all air is removed;

(xi) that the forms are placed in a food grade plastic or aluminium or stainless steel tray so that the forms of the traditional dairy product drip;

(xii) that the trays after the first half hour shall be placed in a place where they can be cooled where the temperature shall be kept between 7°C and 12°C;

(xiii) that these forms of the traditional dairy product shall be turned over every two (2) hours for three or four times to dry up in a uniform and homogeneous manner;

(xiv) that these forms of the traditional dairy product shall be extracted out of their containers after twenty-four (24) hours;

(xv) that all this process of the manufacture of the traditional dairy product can take place in environments that do not have temperature control;

(xvi) that the traditional dairy product that shall be placed on the market in a fresh state can at this point be packed in an acceptable way and as described for that traditional dairy product;

(xvii) that in the case of a traditional dairy product that shall be dried, this shall be placed in a place to dry in accordance with the method described in the recipe for the production of the traditional dairy product. This drying can take place in a ‘*qanni’* or ‘*nemmusiera’*;

(xviii) that the storage of the traditional dairy product that has been dried or treated in any other way may take place in a place that does not have temperature control and may be kept in ambient temperature.

(f) when the traditional dairy product is placed on the market, it shall be packed bearing an identification mark that is placed in such a way that it shall be destroyed or broken when the packaging or the wrapping of the product is opened or the product has to be packed and wrapped in a way that it is sealed
so that the wrapping or packaging material cannot be used again once it is opened.