

A focus on **FOOD SUPPLEMENTS**

We have all heard about food supplements and may have taken them one time or another, but to the contrary of what many people might think, food supplements do not refer only to the small tablets containing vitamins and minerals, but also a variety of other products including the nutrient and chemical packed products which are usually taken by persons before, during and after undergoing strenuous exercise.

The term 'food supplement' has lately been mentioned on the local media due to the recent publication of a White Paper on Food Supplements. The main aim of this white paper is to update existing procedures within the legal framework to current needs.

What are food supplements?

Food supplements are concentrated sources of vitamins, minerals, amino acids, fatty acids, and other substances delivered in the form of pills, tablets, capsules, liquid, etc with a nutritional or physiological effect, whose purpose is to supplement the normal diet. Food Supplements are available in a range of doses, and in different combinations.



However, only a certain amount of each nutrient is needed for our bodies to function, and higher amounts are not necessarily better. At high doses, some substances may have adverse effects, and may become harmful. For the reason of safeguarding consumers' health, supplements can therefore only be legally sold with an appropriate daily dose recommendation, and a warning statement not to exceed that dose.

How are food supplements regulated locally?

The main legislation covering food supplements is LN 239 of 2003 – Food Supplements Regulations as amended by LN 327 of 2005 and LN 94 of 2007. This regulation transposes [Directive 2002/46/EC](#) of the European Parliament and Council of 10 June 2002 on the approximation of the laws of Member States relating to food supplements establishes harmonised rules for the labelling of food supplements and introduces specific rules on vitamins and minerals in food supplements. The local legislation stipulates that these items must only be dispensed by a pharmacist, doctor or person with suitable qualifications as laid down by the Food Safety Commission.

For the purpose of Regulation 5.1 (a) of the Labelling and Presentation of Foodstuffs Regulations (LN 483 of 2004), the name under which products covered by the Food Supplements Regulations are sold shall be 'food supplement'.

The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.

However this does not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy.

Procedure to trade food supplements in Malta

The first step to trade in food supplements is to notify the Malta Competition and Consumer Affairs Authority (MCCAA).

The MCCAA will require a copy of label for such notification. At this stage officials may request the trader to notify the Medicines Authority especially if certain ingredients or claims may be considered as medicinal.

There is a fine line between a food supplement and a medicinal and if the product falls to be the latter, different procedures need to be adopted. If the product is registered as a food supplement by MCCAA, the trader is given an acknowledgement.

This notification system is done once per product per trader.

The second step is to register as a trader with the Food Safety Commission.

This is done by registering in the ad hoc form which can be downloaded from <https://ehealth.gov.mt/download.aspx?id=1330> . Once a trader is registered, a unique registration number is given.

The third step is to notify Port Health Services.

The Port Health Services are to be notified forty-eight hours in advance when a consignment of food supplements is to be imported or distributed into Malta.

In the case of food supplements originating from European Union Member states a notification is required on the appropriate form
<https://ehealth.gov.mt/download.aspx?id=1334>.

The Customs Declaration form is required when food supplements originate from non-European Union Member states. Other documentation is required in the case of products originating from EU and non-EU, these include a copy of the commercial document and a copy of the notification issued by MCCA for each product mentioned in the commercial document.

Once the notification or Customs Declaration is favourably processed by Port Health Services, the trader may trade the product in the Maltese territory. One has to ascertain that the premises, stores and vehicles used have to be registered with the Food Safety Commission as well
<https://ehealth.gov.mt/download.aspx?id=1331>

All mentioned forms are downloadable from

https://ehealth.gov.mt/HealthPortal/public_health/environmental-health/health_inspectorate/port_health_services/forms.aspx

Importation or distribution of food supplements for retail

The majority of the food supplements in the local market are traded either by wholesalers for further retail and also by individuals for personal use. Between January and December of last year, the Port Health Services have processed 6,981 import declarations for food supplements imported by wholesalers.

Importation or distribution of food supplements and medicines for personal use

Last year, officers at the Port Health Services and Port Medical Services have vetted 10,939 importations of food supplements and medicines intended for personal use.

A number of these packages were rejected for various reasons, the most common being improper labelling of product, prescription not presented and also because the product was being recalled.

Recent recalls for food supplements

Annually a number of food supplements are recalled mainly through the Rapid Alert System for Food and Feed (RASFF).

This is a web based 24 hour/7days-a-week tool enabling quick and effective exchange of information between Member States when risks to human and animal health are detected in the food and feed chain. In fact five different food supplements were recalled through this system during the current year. The reasons for such recalls included irregular labelling, the use of unauthorised substances in the product and also due to reported adverse health reactions.

In the past six years, the number of specific food supplements recalled were as follows:

Year	Recalls
2012	2
2011	0
2010	3
2009	8
2008	0
2007	23

Whenever there is a recall for food supplements, the Environmental Health Directorate issues a press release to inform the general public of the hazard involved.

The white paper on the Importation and Sale of Food Supplements

The white paper on food supplements can be found at the following link:

<http://ehealth.gov.mt/download.aspx?id=9820>.

The consultation process with the public and stakeholders, including the NGOs started on the 2nd of December 2013 and contributions can be made up till the 17th January 2014.

References

Food Supplements: <http://www.efsa.europa.eu/en/topics/topic/supplements.htm>

Food supplements: who needs them and when?

http://www.eufic.org/article/en/artid/Food_supplements_who_needs_them_and_when/

The Editorial Team

Author

D. Rota

Editors

D. Rota

S. Sammut

Contributors

Health Inspectorate Services

Design & layout

P. Grech

Postal and visiting address

The Environmental Health Directorate
Continental Business Centre,
Old Railway Track,
Santa Venera SVR9018,
Malta

Phone +356 21 337 333

Fax +356 21 344 767

Links

Web www.ehealth.gov.mt

Complaints complaints.ph@gov.mt

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Direttorat ghas-Saħħa Ambjentali
Environmental Health Directorate