EPF Position Statement on Information to Patients on Food and Nutrition

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Preface

For many people, attaining good nutrition is not simple. Some medical conditions mean that even when a person has good eating habits and makes healthy nutritional choices, achieving good nutritional health remains challenging.

This position statement reflects EPF’s preliminary position on the topic of information to patients on food and nutrition, to be explored further in the coming years.

This document has been developed by the EPF Secretariat in consultation with the EPF membership and experts representing the patient perspective in the field.

In line with its responsibilities as an agent for public health, for our specific constituency, EPF will in 2018 and onwards elevate its strategy in the sphere of information to patients on nutrition, with a particular accent on medical nutrition.

The objectives of this preliminary position are to:

- Raise awareness of the role of nutrition and diet in managing long-term conditions, maintaining optimal health and quality of life;
- Coordinate the patient perspective on the topic of information to patients on nutrition;
- Emphasise the importance of health literacy and informed decision-making concerning nutrition;
- Outline shortcomings in existing policy and legislation from the patient perspective.
Introduction

1.1 NUTRITION: FROM BARE NECESSITY TO AN ESSENTIAL COMPONENT OF DISEASE MANAGEMENT

Links between nutrition and health have been known since ancient times.¹ Evidence shows that nutritional foods are beneficial to good health outcomes, nevertheless, the burden of disease associated with poor nutrition continues to grow in Europe.

Malnutrition refers to deficiencies, excesses or imbalances in a person’s intake of energy and/or nutrients. The term malnutrition covers 2 broad groups of conditions. One is ‘undernutrition’—which includes stunting (low height for age), wasting (low weight for height), underweight (low weight for age), disease-related malnutrition (undernutrition triggered by ill health), and micronutrient deficiencies or insufficiencies (a lack of important vitamins and minerals). The other is overweight, obesity and diet-related noncommunicable diseases (such as heart disease, stroke, type 2 diabetes and cancer).² To determine the risk of malnutrition among patients (at all levels of care), screening of malnutrition is key. Similarly, there are efforts to be made in the training and awareness of health professionals on this subject.

The prevalence of overweight and obesity is increasing in nearly all countries.³ Unhealthy diets, overweight and obesity contribute to a large proportion of noncommunicable diseases, including food allergies and intolerances – lifelong or for a certain period of life. National surveys in most European countries indicate excessive consumption of saturated fat, trans fats, sugar and salt, as well as low consumption of vegetables, fruits and whole grains, insufficient intake of minerals and vitamins, and increasing numbers of people with obesity, all of which not only shorten life expectancy, but also harm the quality of life. Such unhealthy diets can also lead to extended periods of living with poor health.

This increase in overweight and obesity should not be solely attributed to poor diet choice. It is also important to acknowledge that food manufacturers should play a larger role in tackling the issue in not simply displaying the nutritional values clearly on their products but developing means of decreasing the amount of detrimental additives e.g. the amount of added sugar in “healthy” branded breakfast cereals or in low fat products to compensate for the loss of taste and texture after the fats have been removed.

² http://www.who.int/features/qa/malnutrition/en/
Simultaneously, in some vulnerable groups, undernutrition remains a concern, including in the frail elderly.

Less well-known is the important role that nutrition plays in both health and chronic disease management. Indeed, for many people attaining good nutrition is not a simple question of having good eating habits. Some medical conditions mean that even when a person makes good nutritional and lifestyle choices, achieving good nutritional health remains challenging. Furthermore, the condition(s) of the patient or the institution where he/she is treated can condition his/her nutritional status, which is vital for recovery.

Disease-related malnutrition, is undernutrition triggered by ill health. Disease-Related Malnutrition is a condition characterized by inadequate intake of energy, protein, and/or micronutrients as a result of a diverse number of diseases or their treatment, and it impacts individuals at all stages of life, from infancy to old age. It is estimated to affect one if four adult hospital patients\(^4,5,6,7\) and one in three homecare residents\(^8,9,10\). At the same time, the effects of malnutrition can then complicate the disease itself, leading to a vicious cycle of complications.

Research on the effects of nutrition on human health are still ongoing and very much needed as is further research on the associations between low socio-economic status and the consumption of unhealthy products. Increasing income inequality is shown to have an impact on inequalities to healthy nutrition in terms of access and greater vulnerability for the development of chronic diseases.\(^11\)

### 1.2 BACKGROUND AND POLICY CONTEXT

Nutrition is a priority for many governments and international institutions. Most Member States have government-approved policies that aim to promote healthy diets, tackle the growing rates of obesity, and ensure nutrition and food security. Furthermore, policy

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developments from across Europe indicate that improvements to nutrition and diet require the engagement of many different government sectors and will need to involve action by both public and private sectors.

The EU is also tackling the area of nutrition from different angles (with activities and policies on obesity\(^\text{12}\), nutrition and ageing\(^\text{13}\)), with the work of the Directorate General on Health and Food Safety, including various areas connected to nutrition\(^\text{14}\) (labelling, food safety, food fraud, etc).

The recent WHO European Food and Nutrition Action Plan 2015–2020\(^\text{15}\) encourages action in a range of policy areas through a whole-of-government, health-in-all-policies approach. The goal of which is to improve the availability, affordability and attractiveness of healthy foods, with a view to improving the overall quality of the population’s diet and ultimately health and well-being. Until now, however, little attention has been given to the lactose or gluten-free foods for example.

At an international level, the WHO has for many years provided guidance to countries regarding the link between health and nutrition. In 2016, the United Nations General Assembly agreed on a resolution proclaiming the UN Decade of Action on Nutrition from 2016 to 2025.\(^\text{16}\) The main aims are to intensify action to end hunger and eradicate malnutrition, and ensure universal access to healthier and more sustainable diets. The resolution calls on governments to set national nutrition targets for 2025 and milestones based on internationally agreed indicators.

1.3 EPF’S PREVIOUS WORK

EPF initiated its work in the nutrition sphere in 2012/2013, with our contribution and endorsement of a book on patients and nutrition entitled ‘Patient Perspectives on Nutrition’\(^\text{17}\). The book includes an anthology of patients’ needs and experiences in relation to nutrition and its critical role in enhancing treatment and care of patients with serious chronic conditions. This book provided the stimulus for a Memorandum of Understanding between EPF, the European Nutrition and Health Alliance (ENHA), and the European Genetic Alliance Network (EGAN), and commitment to collaborative activities to raise awareness on the nexus between nutrition and an effective, integrated care continuum for patients.

\(^{13}\) https://ec.europa.eu/eip/ageing/about-the-partnership_en
\(^{14}\) https://ec.europa.eu/food/safety_en
\(^{15}\) http://www.euro.who.int/__data/assets/pdf_file/0008/253727/64wd14e_FoodNutAP_140426.pdf
\(^{16}\) http://www.who.int/nutrition/GA_decade_action/en/
\(^{17}\) http://www.eu-patient.eu/contentassets/3998bf037bca4ddc890b934a3d1b460d/patient_perspectives_on_nutrition_-1.pdf
This collaboration formed the basis of numerous initiatives at EU and national level to drive forward nutrition through the lens of patients, and collaboration with a major European campaign – ONCA - Optimal Nutritional Care for All.18

A recent milestone was a European Patients’ Conference on Nutrition in June 2017, which aimed to explore the current state-of-play of various patient organisations in the field of nutrition in relation to prevention, treatment and management of disease, and discuss potential future steps in the area of nutrition. The resulting recommendations19 from this conference make the bridge between more generic awareness activities to more strategic focused work to drive nutrition as intrinsic to patient outcomes.

EPF, in line with its responsibilities as an agent for public health, for our specific constituency, has following this recent conference decided to elevate its strategy in the sphere of nutrition, with a particular accent on medical nutrition.

Building on EPF’s work on health literacy and information to patients, and EPF’s involvement in the European Innovation Partnership on Active and Healthy Ageing Functional decline and frailty action group, EPF will work together with members to consider the outcomes and recommendations of the June 2017 European Patients’ Conference on Nutrition and raise awareness of the role of nutrition and diets in managing long-term conditions and maintaining optimal health and quality of life.

1.4 CONSULTATION PROCESS

This position statement was developed with significant input from EPF’s membership and expert patient representatives. Furthermore, the position statement has undergone consultation with the wider EPF membership, board and secretariat. Many thanks to all EPF members and patient organisations that contributed to this position paper.

2. The importance of food and nutrition in the prevention and management of chronic and long-term conditions

From a patient perspective, the following three-fold categorisation is helpful to understand the different needs and expectations of different groups of patients, and to plan policies accordingly.

18 https://european-nutrition.org/
2.1 NUTRITION IN PRIMARY PREVENTION AND IMPROVED DISEASE MANAGEMENT

The first category relates to the importance of nutrition in primary prevention and improved disease management. This category encompasses nutrition as a preventative and health promotion measure, something that is relevant for all people and for public health. In this area, food and consumer legislation is most relevant, together with public health policies and health promotion and public awareness strategies to inform the public, including patients about healthy diets for example. Although this is very often the focus of consumer protection and public health organisations, patient organisations are also active in this area.

- For example, supplementation with 400mcg folic acid starting ideally 3 months before conception, until the 12th week of pregnancy has been proven to reduce the risk of Neural Tube Birth Defects (NTDs) like spina bifida and anencephaly by up to 72%. Despite being armed with this knowledge for 25 years, up to 2/3 of women are still shown to have suboptimal levels of this vital vitamin during the critical preconception period.\(^{20}\)\(^{21}\) A healthy, varied diet should be considered as an important factor in preconception care. During a child’s first 1000 days – from conception until about two years of age – it grows and develops at an amazing pace and is heavily influenced by environmental factors. The nutrition babies receive before and after birth, affects their health. The latest research data increasingly shows the importance of a balanced diet for the mother-to-be and baby to keep the child healthy – in babyhood and beyond.\(^{22}\)

- Being overweight or obese are risk factors for developing post menopausal breast cancer, which is still not widely known amongst the general public. Consumption of alcohol also increases breast cancer risk so diet plays a role in breast cancer prevention though more research is needed to confirm other specific dietary recommendations.\(^{23}\)

• Overweight or obesity is also a risk factor for developing type II diabetes, cardiovascular diseases for example.

• Nutrients such as protein, calcium and vitamin D are necessary to optimize bone health at all ages. In maternity, during childhood, and particularly in the key growth years during adolescence, good nutrition helps ensure that children achieve their genetic potential for peak bone mass, which sets a foundation for stronger bones in adulthood. In adults, adequate intake of nutrients is important to avoid premature bone loss. In seniors, adequate intake of these nutrients, and sufficient caloric intake, helps to sustain musculoskeletal health and prevent osteoporosis.24

• For congenital heart disease, following medical or surgical attention, a healthy diet is important in order to prevent weight gain which could ultimately harm arteries and the heart.

• For patients with allergy and airways diseases, there is no cure for food allergies, the only protection is the abstention from the allergen causing the reaction. Consumers suffering from allergies must therefore be able to identify the ingredients they are sensitive to. Allergies may cause several symptoms, ranging from gastro-intestinal problems, eczemas, urticarias to airway obstructions and cardiovascular shocks and so information on food allergens is seen as one crucial prevention measure. A challenge for patients with allergies may also be undernutrition.

• Proper nutrition is also crucial for patients with chronic obstructive pulmonary disease (COPD). Cachexia and muscle wasting is a frequent complication in patients with COPD and is characterized by a weight loss. A well-balanced diet is beneficial, not only for the potential gains in the pulmonary status, but also for lowering metabolic and cardiovascular risks. Nutritional supplement therapy has been proved to not only improve undernutrition in COPD patients but is also beneficial in the prevention of the development, progression, and exacerbation of COPD. In order to increase the overall survival rate and decrease morbidity in patients with COPD, the nutritional aspect should be incorporated into the management of this disease.25

2.2 NUTRITION IN THE MANAGEMENT OF CHRONIC CONDITIONS AND BETTER HEALTH OUTCOMES

Making good choices about one’s diet is not just an important way to help prevent the onset of chronic conditions and maintain health.

25 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4936454/
This second category relates to where nutrition has a key part to play in the **management of a chronic condition and health outcome** as well as the importance of nutrition in secondary prevention and **prevention of multimorbidities**. Appropriate nutrition can prevent certain symptoms, delay the onset of complications, and improve health outcomes for certain patients. Eating the right kinds of foods can improve well-being and physical strength, whereas poor nutrition can lead to reduced immunity, impaired physical and mental development, and reduced productivity. Moreover, certain foods will be more appropriate for some patients depending on their chronic condition(s). In this case, nutrition will also have to be adapted according to the patient's needs.

- For example, people with coeliac disease or lactose intolerance are in many cases able to stay well by avoiding certain types of foods. Where a major food group is being excluded, proper nutritional counselling will be necessary to manage the complexity of adjustment needed to maintain a healthy balanced diet. Gluten-free foods would benefit from increased awareness among not only the general public but also among healthcare and medical professionals who have the responsibility to advise patients with coeliac disease to follow a strictly gluten-free diet as at present, this is the only known evidence-based therapy which exists.

- In people who have osteoporosis, foods rich in calcium and protein, as well as adequate levels of vitamin D, will help to sustain and improve musculoskeletal health.

- A key requirement in preventing debilitating complications in diabetes is maintaining good blood glucose (glycaemic) control, blood pressure and cholesterol. This is highly dependent on choosing healthier foods and knowing the nutritional content of foods including carbohydrates, salt and fats. Contrary to popular belief, people living with diabetes do not need to eat special foods. People with diabetes can eat all foods recommended to the general population as part of a balanced diet. However, they need comprehensive nutritional information, backed with education and training, to be able to adequately manage their condition. This may include calculating the amount of carbohydrates, recognizing hidden sugar within food ingredients and knowing the amount of salt and fats. Clear and easily understandable food labelling is therefore essential for people with diabetes to make the best everyday food choices. Additionally, timing is everything: people taking insulin or some glucose-lowering medication must match the timing and dosage of their medication with the quantity and nature of the carbohydrate contained in their meal to help maintain good or near normal blood glucose control. Carbohydrate-related information on the front of pack label therefore significantly supports good diabetes care.  

• Many patients with long term Rheumatic and Musculoskeletal Diseases (RMDs) are aware of how important nutrition and food selection is for their wellbeing, and they are very cautious and sensitive on selecting their daily dietary products. Research has shown interaction between food products and disease. Crete’s Rheumatic patients’ association has developed a lay-language guide\(^\text{28}\) for patients with rheumatic diseases, where the impact of different types of foods on health and rheumatic disease is explained. For example, red meat contains fats, which slowly cause blockage of the blood vessels and therefore may cause strokes, coronary heart diseases or myocardial infarction. Patients with inflammatory rheumatic diseases (e.g. rheumatoid arthritis, psoriatic arthritis etc.) have, by nature, some vascular damage. For this reason, limited consumption (once per week) of red meat is recommended to such patients.

• Cancer prevention includes eating a variety of vegetables and fruits and limiting red meat consumption. People with cancer need to keep a balanced diet, maintain a healthy weight and limit alcohol intake.\(^\text{29}\) This is an important step in reducing risk of cancer recurrence, second primary cancers, and improving physical and emotional health.\(^\text{30}\) Cancer type, stage, and treatment all need to be taken into consideration when deciding if any foods must be avoided. Consuming large doses of vitamins or antioxidant supplements is not recommended, as some vitamins and / or herbal supplements can interfere with cancer therapy.\(^\text{31}\) Urgency and relevance of nutrition for cancer patients, has been clearly demonstrated. In a study performed among 907 people with cancer, 90% did not receive any information about cachexia from their health professionals. Whereas, almost 70% reported that they lost weight after the cancer diagnosis. More than 70% of the respondents didn’t know the meaning of the term ‘cachexia’ (weight loss caused by cancer).\(^\text{32}\)

• For patients with kidney disease, attention to nutrition is particularly relevant before and during dialysis. Most patients on dialysis need to limit the amount of sodium, potassium, and phosphorus in in their diet. Needs may vary depending on the type of dialysis treatment you receive.

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\(^{32}\) ECPC (European Cancer Patient Coalition). Living Well During Cancer Treatment. Brussels: ECPC; 2017
Malnutrition (disease-related malnutrition or other) must be treated in itself, independently of the associated disease.

2.3 MEDICAL NUTRITION

For some types and phases of disease it is not possible to maintain a proper nutritional status and/or avoid disease symptoms with personalised diets and standard foods alone. In such cases specialised nutritional products (medical nutrition) are needed to supplement the diet, or to replace food. In these cases, patients are partially or entirely dependent on medical nutrition. This might be because of a (temporary) inability to intake food orally or because of the inability to process some parts of food (specific nutrients, or other substance).

Specialised dietary products may be needed temporarily because of an acute health threat. With such products the nutritional gap is closed until a person is able to return to their usual diet. In other cases, specialised products may be needed for the long term, sometimes even permanently, and will become an integral part of disease management throughout life.

It is also important to note however that patients may not be able to maintain a good level of nutrition orally due to a modified diet as is the case with swallowing problems. Patients need advice and guidance on how to ensure that their modified diet (e.g. pureed food or soft moist diets) contain adequate levels of nutrition as naturally certain items will be omitted from a safety perspective.

Medical nutrition may be enteral (via the stomach) or parenteral (via the vein). Such nutritional formulas, either prepared in hospital pharmacies or by the medical nutrition industry, are given through a special feeding tube (enteral) or intravenous catheter (parenteral). Most often this can be done in one’s own surroundings, however it is sometimes given in hospitals, especially in more critical periods.

- For inflammatory bowel diseases such as crohn’s disease and ulcerative colitis, oral nutritional supplements, feeding via a tube or feeding intravenously may be necessary to ensure that nutritional needs can be met.

- For mental health problems such as eating issues/disorders, including anorexia, bulimia or other specified feeding or eating problems, medical nutrition can also play an important role in the recovery journey of the patient if addressed as part of an integrated approach to care (i.e. together with psychological support, counselling, participation in support groups). People experiencing eating problems may develop dangerous eating habits (such as restriction, privation, over eating) and may need support with re-adjusting their diet as part of their recovery. That is why medical nutrition is considered an important (but not sole) aspect of treatment for eating issues, as it can help stabilise the patient’s health and medical condition as a result of
the eating issue. It is also important to note that persons experiencing eating issues should be fully involved in the decisions taken around their treatment and recovery journey.

- For preterm, extremely low birth weight, or ill infants, early intravenous feeding may be necessary to ensure appropriate energy intake and consequently improve developmental outcomes, if nutrient needs cannot be met by enteral feeding. 33.

- Evidence shows that 39% of patients with cancer experience malnutrition. 34,35 This figure is perceived to be underestimated by patients and relatives and overestimated by physicians. Malnutrition in cancer is associated with poor response to therapy, increased susceptibility to treatment-related adverse events, as well as poor outcome and quality of life. 36 Regular screening for malnutrition is therefore important for cancer patients. Timely and appropriate use of medical nutrition can improve energy intake 37 and reduce weight loss in cancer patients. 38.

Such patients are potentially at risk of or may already be malnourished or more specifically undernourished. ‘Malnutrition’ in its broadest sense means poor nutrition and encompasses both undernutrition and overnutrition. One definition for malnutrition that is commonly used is ‘a state of nutrition in which a deficiency, excess (or imbalance) of energy, protein, and other nutrients causes measurable adverse effects on tissue/body form (body shape, size and composition) and function, and clinical outcome. 39

The above categorisation is not absolute and the limits between the identified areas may not always be clear. Many disease areas, such as cancer, may fall under all three categories at the same time because of the variety of affected body functions and the (increasingly often) identified causes of the disease.

- For patients with Epidermolysis Bullosa (EB), a rare genetic skin blistering condition, clinicians will endeavour to ensure from birth that the patient is sustained with the correct diet of nutrients necessary for optimal growth, bone health, wound healing (among others) as many nutrients are lost through blistering and skin breakdown. Consumption of supplements is common. Depending on the status of the disease,

34 https://www.ncbi.nlm.nih.gov/pubmed/28135422
Enteral feeding may be deemed the best course of action to maintain proper nutritional status of the patient. An important factor for EB patients is also fear of eating, particularly in children, if mouth, oesophageal, and/or rectal blisters create problems for feeding.

3. EU legislation related to information to patients on food and nutrition

There is a large body of EU law that deals with food law or other aspects of nutrition. A part of this legislation concerns food production. Plant health and biosecurity, plant reproductive material, pesticides and GMOs are all (partly) regulated under EU law.40 Another part of the legal framework is concerned with animals41 and issues such as: meat production, milk and milk products, as well as animal feed.

The EU's **food safety** policy covers food, from farm to fork. It is designed to guarantee safe, nutritious food, as well as clear information on the origin, content, labelling and use of food. The European Union's food safety policy aims to protect consumers, while guaranteeing the smooth operation of the single market. The EU has agreed standards to ensure food hygiene, and to control contamination from external substances, such as pesticides and different toxins. Imports (e.g. meat) from outside the EU are required to meet the same standards and go through the same checks as food produced within the EU. The common agricultural policy (CAP) has a role in ensuring the provision of safe foods.

The Commission's Strategy to address the issues of **overweight and obesity**, by adopting the White Paper ‘A Strategy on Nutrition, Overweight, and Obesity-related health issues’42 focuses on action that can be taken at local, regional, national and European levels to reduce the risks associated with poor nutrition and limited physical exercise, while addressing the issue of inequalities across member states. This strategy encompasses a range of Commission policies including **food labelling**43 and **health and nutrition claims**44 related policies with the purpose of improving nutrition and preventing overweight and obesity.

The first two sections below, are not of specific focus on patients, but affect the general population. The last sections are focused on food-law that affects patient in particular.

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40 https://ec.europa.eu/food/plant_en
41 https://ec.europa.eu/food/animals_en
43 https://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation_en
44 https://ec.europa.eu/food/safety/labelling_nutrition/claims_en
3.1 THE GENERAL FOOD LAW REGULATION

When it comes to the regulation of food itself, the most comprehensive legislative act is the General Food Law Regulation\textsuperscript{45}. This Regulation, adopted by the European Parliament and Council in 2002, lays down the general principles and requirements of food law. The General Food Law Regulation was drafted following a series of food incidents in the EU in the late 1990s, including the BSE (bovine spongiform encephalopathy) outbreak and the dioxin scare. It is the act underpinning current EU food and feed legislation and defines its general principles, requirements and aims. This is a horizontal framework, on which all EU and national food legislation is based. The general principles of this Regulation cover all stages of the \textit{food-cycle} (production, processing and distribution). The main aim of the Regulation is to guarantee a high level of protection of human life and health and the protection of consumers’ interests and ban the sale of foods dangerous to health or unfit for consumption. Factors such as normal conditions under which food is used by the consumer; \textbf{information provided to the consumer}; the effect on health, in the short and long term; cumulative toxic effects; and specific sensitivities of certain consumer groups, for example children and people with food intolerances, are taken into account.

The Regulation also sets up the \textbf{European Food Safety Authority}\textsuperscript{46}, which provides scientific and technical support to the European Commission and EU countries in all areas impacting on food safety. It is also responsible for coordinating risk assessments, identifying emerging risks and advising on crisis management.

3.2 BIOLOGICAL AND CHEMICAL SAFETY

European food law also deals with specific aspects such as the \textbf{biological}\textsuperscript{47} and \textbf{chemical}\textsuperscript{48} safety of food.

When it comes to biological protection, legislation is concerned with eliminating or minimising risks related to bacteria, viruses, parasites, prions and biotoxins. Some of these hazards have posed serious risks to public health, such as Salmonella, Listeria monocytogenes, biotoxins in live molluscs or BSE. In this context, the legislation deals with aspects like \textbf{food and feed hygiene}.

Food law pertaining to biological safety could benefit from revision. The rules relating to hazards such as mycotoxins or heavy metals found in cereals (e.g. corn and rice) should be revised and is currently on the agenda of the European Commission. Some groups of

\textsuperscript{45} http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002R0178&from=EN
\textsuperscript{46} http://www.efsa.europa.eu/
\textsuperscript{47} https://ec.europa.eu/food/safety/biosafety_en
consumers and patients who are gluten intolerant for example consume much higher amounts of these cereals, which are used to replace gluten-containing wheat, rye and barley. On a daily basis, these patients consume a much higher amount of these grains compared to the general population. Therefore, the limits of dangerous and health damaging raw materials biotoxins/mycotoxins content for specialised gluten free products should be the same as for baby food or pharmaceutical products for example.

Chemical safety concerns chemical substances that are used in food production and distribution. Such chemicals might be food additives, flavourings, contaminants, residues of veterinary medical products, and food contact materials. Most of those substances play an important role but can have negative effects. For example, in order to keep food hygienic and attractive it needs to be kept in containers that are made of chemical substances such as plastics. These clear benefits of the use of chemicals in food production and distribution have, on the other hand, to be balanced with potential risks for the health of the food consumer due to side effects and residues of these chemicals. That is exactly what this part of the legislation deals with.

### 3.3 FOOD INFORMATION TO CONSUMERS

#### 3.3.1 GENERAL LABELING

A new EU Regulation on the provision of food information to consumers\(^{49}\) was adopted in December 2011, with some major parts applied as of 2014. The new law combines 2 Directives into one legislation: 2000/13/EC - Labelling, presentation and advertising of foodstuffs and 90/496/EEC - Nutrition labelling for foodstuffs.

These new EU food labelling rules aim to ensure that consumers receive clearer, more comprehensive and accurate information on food content, helping them make informed choices about what they eat. The obligation to provide nutrition information under these new rules has applied since 13 December 2016.

The legislation has brought some major changes that affect the food products that are sold around Europe:

- Compulsory nutrition labelling
- Referring to the energy value or energy value and fat, saturates, sugars and salt
- Although not compulsory, other nutrients such as vitamins, fibres, or minerals may also be referred to
- Compulsory allergen labelling – the regulation identifies a list of 14 allergens (eggs, milk, fish, crustaceans, molluscs, peanuts, tree nuts, sesame seeds, cereals containing gluten,

soybeans, celery and celeriac, mustard, lupin and sulphites), where labels on food products must be emphasised and available at all times for consumers.

Although this labelling is not directed to the needs of patients in particular, clear and harmonised labelling is clearly a considerable advantage for patients and it can have a great impact on the life of people with chronic conditions, as explained above.

Food labelling is also relevant to primary prevention. For example, women of childbearing age actively choosing to consume foods that have been fortified with folic acid to achieve their optimal daily intake.

Generally, the patient community welcomed this new food labelling regulation. It is useful and allows for far more informed decisions when purchasing products. Satisfaction for this regulation is however somewhat contested as it does not go far enough in making labelling understandable to lay persons and easily readable (the font size is still too small).

Patient, health and consumer organisations were generally favourable of the front-of-pack colour-coded nutritional labelling which is proven to be the best way of informing consumers at a glance. Research shows that use of colour-coded labels, also known as traffic light labelling, kept in a single format across food products, is one of the most effective ways to communicate nutritional information to people.50

- The European Federation of Allergy and Airways Diseases Patients’ Associations (EFA), considers the EU regulation on food information for consumers to be a positive step to improve health and quality of life for people with food allergies. Sometimes people, and even policy-makers, consider allergy as a trivial disease, but they do not realise that the allergy might result in poor nutrition, quality of life, fear, restrictions, social isolation, and sometimes even death. In fact, 8% of food allergic people might have acute anaphylaxis reactions that could be fatal. EFA advocates to strengthen the regulation with the following measures:
  - The full food ingredient list should always be indicated both for pre-packed and non-pre-packed foods (currently, there are exceptions based on the size of the package of the food), as other people may be allergic to other substances than to the 14 identified allergens; written information on the presence of allergens in non-pre-packed foods is the most reliable means to provide detailed information for allergic consumers, unless the person that prepared the food is available to list the ingredients to the consumers; and precautionary labelling i.e. “may contain” mention should be abolished after the establishment of “safe thresholds”.51

51 http://www.efanet.org/food-labelling
The regulation is also an important breakthrough for people living with diabetes as it paves the way for better information and helps consumers make informed and healthy choices with respect to intake of sugar. Further improvements are, however, needed. The European region of the International Diabetes Federation recommends the introduction of clear, unambiguous, colour-coded front of pack labelling which give total sugar content, including all types of sugar, those with alternative names (such as high fructose corn syrup).\(^{52}\)

3.3.2. REGULATION ON FOODS FOR SPECIFIC GROUPS

Parallel to the general labelling Regulation, another EU Regulation on foods for specific groups\(^{53}\) was adopted in 2013 (and is applicable since 2016). This regulation sets the rules for foods intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. The content and marketing of food products specifically created for and marketed for these groups, is regulated more strictly under this piece of legislation.

3.3.2.1. Dietary Foods for Special Medical Purposes

When it comes to patients whose dietary management is under medical supervision, the legislation is in a transitional phase. For the time being, an EU Directive on dietary foods for special medical purposes\(^{54}\) (i.e. often abbreviated as FSMP and also called: tube feeds, sip feeds and other oral nutrition supplements) dating from 1999 is still applicable. The legislation applies to foods intended for patients living with a disease, disorder or medical condition who are unable to meet their nutritional requirements with normal food. The Directive, which defines and categorises the products covered, also includes guidelines on the micronutrient content and labelling requirements for such products.

In 2015, the Delegated EU Regulation\(^{55}\) supplementing the 2013 EU Regulation on foods for specific groups\(^{56}\) as regards the specific compositional and information requirements for food for special medical purposes, revised the 1999 Directive and will fully replace it as of February 2019 (or one year later for dietary foods for special medical purposes for infants).

The changes envisaged are not major (with some exceptions), and the existing rules for a big part will be maintained. The main need for this new legislation was to bring the labelling aspects in line with the General Labelling Regulation (see section 4.3). The legislation revised some labelling requirements as well as the composition of FSMPs, including the minimum and maximum levels of micronutrients, such as vitamins and minerals that they may contain. One


\(^{55}\) http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32016R0128

of the main changes that has been introduced, is the prohibition to make nutrition and health claims on foods for special medical purposes, in order to ensure legal clarity and avoid inappropriate promotion of products.

3.3.2.2. Allergen declaration
The EU Regulation on the provision of food information to consumers\(^\text{57}\) states that the labelling of presence of any ingredient, processing aid, a substance or product causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form is compulsory. Since the latest rules are applicable (since 20 July 2016), the requirement does not only apply to pre-packed food, but also to foods that are served in restaurants for example. However, the use of precautionary labelling about cross contamination (e.g. “may contain traces of nuts, soja”), remains a challenge for people with coeliac disease as well as for those with allergies generally. Poor use of such labelling is widely recognised as harmful to such patients. In this respect, there is a desire for further legislation in this area in order to support self-care.

3.3.2.3. Gluten-free Food
Gluten-free food is regulated by the 2011 regulation on the provision of food information to consumers and the 2014 implemented regulation on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food. The 2011 regulation on the provision of food information to consumers provides a high-level guarantee and security for patients eating gluten-free foods lifelong. The compulsory labelling of gluten-containing ingredients is applied to pre-packed, non-prepacked food and food that is served in restaurants, as gluten is one of the 14 main food allergens. A series of legislations\(^\text{58, 59}\) harmonise the requirements for when a food may be labelled “gluten-free” or “very-low gluten”. The food ‘suitable for people intolerant to gluten’ is produced, prepared and/or processed to reduce the gluten content or to substitute the gluten-containing ingredients with other ingredients naturally free of gluten.

3.3.3. FOOD FOR PEOPLE WITH DIABETES
On basis of a repealed Directive on foodstuffs intended for particular nutritional uses\(^\text{60}\) no longer in force, the Commission was required to conduct a study on the aptness of special legislation for people with diabetes. The report\(^\text{61}\) that was produced by the Commission in 2008 concluded that “people with diabetes should choose a healthy diet and should be able

\(^{60}\) http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009L0039
to do so from normal foods. In the light of these reviews there are no grounds for developing specific compositional requirements for foods intended for people with diabetes”.

The conclusion of the Commission report that the dietary regimen should be essentially the same as for the people without diabetes does not stand today, because it is too simplified in the light of the new knowledge. The basis of the dietary regimen should be as close as possible to the standard food and to the patients’ habits and lifestyle, however, it is essential to reduce sugar, especially fastly reabsorbed carbohydrates, and especially added sugar.62 Furthermore, the technology of the manufacturing of dietary products to be used in diabetes has considerably improved since 2008 and the availability of these products is different throughout Europe. A European wide survey on this topic would be useful.

3.3.4. FOOD INTOLERANCE

Nutritional guidance by specialists is usually general, assuming everyone can take the recommended healthy food. In fact, it is important to test that different categories of people can tolerate various food substances even if these are proven to be healthy before taking them. More and more people have food intolerance in addition to their health condition. In this respect, further clarification may be needed on how the consumer can be reliably informed that the nutrition information on food labels is actually what he/she needs or not.

3.3.5. MARKETING AND ADVERTISING

Article 9 (2) of the current Audiovisual media services directive63 encourages media service providers to develop codes of conduct curtailing the advertising of “unhealthy” food and drinks in children’s programmes. It states that:

“Member States and the Commission shall encourage media service providers to develop codes of conduct regarding inappropriate audiovisual commercial communications, accompanying or included in children’s programmes, of foods and beverages containing nutrients and substances with a nutritional or physiological effect, in particular those such as fat, trans-fatty acids, salt/sodium and sugars, excessive intakes of which in the overall diet are not recommended.”

While all EU countries have notified transposition measures, issues of implementation are still ongoing in some countries.

The proposal for an updated EU Audiovisual Media Services Directive, presented by the European Commission in May 2016 64, is currently being debated within the European

Parliament. The overarching goal of the proposal is to bring about a balance between competitiveness and consumer protection. The proposed modifications aim at reinforcing those rules seeking to protect the most vulnerable. For example, the revised directive encourages the adoption of self- and co-regulation for the existing rules seeking to protect the most vulnerable (alcohol advertising, fatty food, minors, etc.).

3.4 PARENTERAL NUTRITION

Contrary to enteral nutrition (via the stomach), considered as a “food”, which must comply with the EU Directive on dietary foods for special medical purposes, as mentioned above, parenteral nutrition (via the vein) is considered to be a “medicinal product”, and is therefore regulated under one of the three possible procedures for marketing of medicinal products.65

4. EPF statement and recommendations

The topic of nutrition is very broad and multi-faceted, affecting patients and consumers in diverse ways. Listed below are some recommended key actions and aspects that should be considered in order to take patients’ needs further into account, and to provide improved information on food and nutrition to patients.

4.1. FUNDAMENTAL ROLE OF PATIENT ORGANISATIONS

The involvement of patient organisations in any area of policy that affects them is key. In this context of nutrition, the role of patient organisations is vital. As highlighted above, patients are affected by all aspects of nutrition and based on experience have valuable insight to how policies can be improved or better applied. Whether it is about clear labelling and better consumer protection, or food that fits the needs of patients with specific conditions, nutrition affects both the health and quality of life of patients and so patients’ needs, and perspectives need to be considered. Patient organisations can play a key role in educating the public concerning the importance of diet and nutrition as it plays a role in primary prevention and potentially in avoiding recurrence of breast cancer for example.

Furthermore, the ways in which nutrition affects certain disease areas is very often still unknown and even when it is, limited attention is drawn to it. Patient organisations have an equally important role in advocating for further research and involvement of patients in such research.

4.2. INFORMATION AND AWARENESS

Information and awareness are essential to improving public health and patients’ quality of life. Health literacy is a key determinant of health (WHO, 2013).

Low health literacy, or the lack of health literacy-friendly information can make daily life choices difficult for patients, for example “because the information about which types of behaviour or which products are healthy can be contradictory or not fully understood … People shopping do not always easily understand the composition of products such as processed food or judge the accuracy of health claims – since not many of these provide easily understandable information or labelling.” Furthermore, being health literate empowers patients to understand information about their health and make more informed decisions.

The EU Health Literacy Survey showed that around 36% of respondents found it “fairly” or “very difficult” to understand information on food labels, whilst in some countries the number was over half. But besides being an individual challenge, health literacy is also fundamentally about changing systems and organisations to respond better to people’s information needs and to support informed choices.

In the nutrition arena, health literacy-friendly measures recommended by WHO include clear and understandable labelling on foods and beverages, such as via the “traffic light” system; making relevant and understandable information available from reliable sources; and having appropriate regulation in place for example as regards marketing practices.

It is important that research, guidelines, recommendations and good practices concerning nutrition reach patients and citizens. Research and guidelines should be explained and disseminated in a lay-friendly way, and their communication and dissemination should be improved. Patient organisations, healthcare professionals, governments and the wider education system, all have their specific roles to play in this area, if we are to improve health awareness and maximise impact upon the health and lifestyle choices of future generations.

The patient community calls for lay person summaries of recognised guidelines, developed by patient organisations with the support of health professionals.

68 WHO 2013, page 41-42.
As an example, of how patient organisations can contribute, Europa Donna, The European Breast Cancer Coalition, launched Breast Health Day in 2008 to raise awareness of the lifestyle factors relating to breast cancer risk.69

On the other hand, it is important that research and good practices reach policy-makers in appropriate ways. Information and awareness are an imperative for policy making. Especially when it comes to disease-specific research, there are vast amounts of information that policymakers working in the area of food regulation are not aware of, but which once communicated correctly can improve policy.

EPF also supports and promotes further collaboration on nutrition and health information and awareness between consumer and patient organisations. 70

4.3. REGULATORY REQUIREMENTS

Food production is a process with many interests at stake. Nevertheless, food and nutrition’s impact on human health is the most important variable in this equation. Many of the problems faced by patients can be tackled with the right regulatory adjustments. Whether the focus is the production of food, the packaging of it, or the allergens and nutrients it contains, regulatory requirements can assist patients in making the decision that is right for them based on their specific conditions.

Generally, the patient community welcomed the new EU ‘Food Labelling’ Regulation71. It is useful and allows for far more informed decisions when purchasing products. Satisfaction for this regulation is however somewhat contested as it does not go far enough in making labelling understandable to lay persons and easily readable. Similarly, many patient, health and consumer organisations are of the opinion that this regulation missed the opportunity to include compulsory colour-coded front-of-pack nutrition labelling for food and drinks.

Several EPF members have developed recommended measures to further improve the regulation, including front of pack labelling.

- The European Federation of Allergy and Airways Diseases Patients’ Associations believes that the European Union should adopt a comprehensive approach on food labelling, taking into account all aspects relating to legibility, including font, colour and contrast, to guarantee clear legibility and safe choices for allergic consumers; and that the European Commission should be responsible for sharing the best food

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69 www.breasthealthday.org
70 For example BEUC, the European consumer organisation, has produced extensive work on food labelling. See http://www.beuc.eu/food/food-information
labelling examples and practices among EU Member States legislations and drafting and implementing EU-wide guidelines.\textsuperscript{72}

- Aside from front of pack labelling, the European region of the International Diabetes Federation recommends a ban on advertising of sugar-sweetened beverages and high sugar foods to children and adolescents and a revision of healthy eating guidelines to reduce consumption of foods with naturally high sugar content (e.g. certain fruits and fruit juices).\textsuperscript{73}

4.4. RESEARCH

The critical role of nutrition in improving quality of care has been shown. However, as in all areas, continuous research is very important for the development and improvement of policies and legislation. Nutrition is no exemption and, in many areas, especially in research relating to the effects of nutrition on specific chronic conditions, research is underdeveloped and specifically research from a patient perspective. Specifically, with regard to nutrition, new research methods have to be developed to collect the individual experience of patients (in comparison to large trials) in order to support the generation of higher levels of scientifically acceptable levels of evidence.\textsuperscript{74}

The European Region of the International Diabetes Federation for example, calls for further research to be undertaken to establish links between sugar intake and type 2 diabetes.\textsuperscript{75}

4.5. ACCESS TO APPROPRIATE NUTRITION AND REIMBURSEMENT

Patients can face issues to access the appropriate nutrition if reimbursement is not available. Reimbursement for medical nutrition is fragmented in Europe, where reimbursement is decided at country – or even at regional level. Even at country/regional level, reimbursement remains partial and diverse, and can depend on the care setting (hospital/community), on the indication (cancer, stroke,) on the patients age, on the dosage recommended by the healthcare professional, etc. This limits access to appropriate nutritional care for patients although there is evidence that appropriate nutritional support is both effective and cost-efficient:

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\textsuperscript{72} http://www.efanet.org/food-labelling
\textsuperscript{73} http://www.eu-patient.eu/globalassets/library/publications/added-sugar-final_idf-europe-position.pdf
\textsuperscript{74} http://www.beyondrct.net/
\textsuperscript{75} http://www.eu-patient.eu/globalassets/library/publications/added-sugar-final_idf-europe-position.pdf
Malnutrition is associated with increased morbidity in both acute and chronic diseases: the extra cost of treating a patient with malnutrition is 2 to 3 times greater than a non-malnourished patient.\textsuperscript{76,77,78,79}

Different forms of medical nutrition have demonstrated clear clinical benefits and cost-savings for healthcare systems:

- Oral nutritional supplements have been shown to reduce complications by 25%, reduce readmissions by up to 33% and reduce overall cost of hospital care by 12%.\textsuperscript{80}
- Enteral nutrition is associated with reductions in mortality and complications\textsuperscript{81} in hospital patients, including patients who are critically ill.\textsuperscript{82}
- Parenteral nutrition has demonstrated nutritional, functional, and clinical benefits\textsuperscript{83}, and data are accumulating to show that it is a cost-saving therapy in intensive care units.\textsuperscript{84,85}

A common example is that of gluten-free products which several studies have shown to be 3-4 times more expensive than gluten containing equivalents. Across Europe, patients with conditions preventing them from tolerating gluten, such as coeliac disease, are not always fully or even partially compensated for the extra expenses they need to cover in order to access these foods and maintain a balanced diet.

\textsuperscript{76} See list of references in MNI publication: Better care through better nutrition : Value and effects of Medical Nutrition – a summary of the evidence base. MNI. 2018, p. 86-97. \textit{Link}.
\textsuperscript{77} The cost of malnutrition in England and potential cost savings from nutritional interventions, BAPEN and the National Institute for Health Research Southamption Biomedical Research Centre, 2015. \textit{Link}.
\textsuperscript{83} See list of references in MNI publication: Better care through better nutrition: Value and effects of Medical Nutrition – a summary of the evidence base. 2018 –p. 229-260. \textit{Link}.
Some countries have systems of government support in place in this respect – for instance, coeliac patients in France benefit from partial reimbursement. In Italy, vouchers are available to diagnosed coeliac patients to buy a selection of gluten free foods - but there are still wide disparities across Europe, and pressure on public health spending in several European countries are putting even established schemes at risk.

Additionally, some patient organisations recommend that Members States reduce tax charges on gluten-free products, which in some countries have a valuable added tax of 27%; and increase tax charges ‘less healthy’ products such as processed snacks and sweets.

Lack of financial support can contribute to nutritional deficiencies, given the importance of staple foods such as bread to nutritional requirements, as well as to reduced compliance with the gluten free diet, which in turn can increase the risk of complications of the disease.

EPF recalls article 35 of the EU Charter of Fundamental Rights86 and recommends that the EU should support patients’ access to nutrition appropriate to their condition as part of the fundamental right of access to preventive health care and to medical treatment.

In this respect, EPF calls on the EU and Member States to guarantee equity and justice in terms of access and reimbursement of nutritional care among the different territories and pathologies.

4.6. DISEASE-SPECIFIC NEEDS

Much of the information on nutrition is very much linked to a specific condition. Very often what can be very beneficial for one person can be a major obstacle for the other. Disease-specific needs are a cross-cutting issue affecting all identified categories of major importance; whether it comes to research, awareness, regulatory requirements or reimbursements, the asks of each patient group might differ. At the same time, consolidating this information, while still being able to take into account the needs and sensitivities of each group is of great importance.

4.7. KEY RECOMMENDATIONS

- EPF supports the recommendations resulting from the recent EU Patients’ Conference on Nutrition on: strengthened European collaboration on food and nutrition; EU-wide education and dissemination of existing information and materials, food labelling and consumer safety, enhanced innovative scientific research practices that support patients drive for self-care; prevention throughout the life-cycle; the development of a health promoting and healthy food environment and strengthened

collaboration between key stakeholders, and suggests that they be further defined, and include more specific recommendations and proposed actions.

- EPF proposes the introduction of a **mandatory front-of-pack labelling scheme and European harmonization** in this regard. A group of French public health, patient and consumer organisations have recently launched a petition calling for ‘Nutri-Score’, a simplified nutritional labelling tool, to be implemented in order to reduce unclear messaging from certain industry sectors.
- Patient organisations should be **meaningfully involved** in developing legislation that ensures manufacturers display the information patients want on labels in a way that is clear, easy to read, use and understand in order to help them make an informed choice when buying food.
- EPF promotes further **collaboration between consumer and patient organisations** on nutrition and health information and awareness.
- Patient organisations should be involved in **research** pertaining to the ways in which nutrition affects certain disease areas.
- Nutritional screening should be included in overall disease management programmes and nutrition counselling should be available and integrated in all hospitals.
- Access to appropriate and timely nutritional care should be guaranteed to all patients at risk of malnutrition.

## 5. Conclusion

This position statement will be a stepping-stone towards a closer focus in 2018.

In 2018, in line with EPF’s objective of information to patients, we will develop comprehensive lay person summaries of recognised guidelines in the sphere of nutrition, together with interested EPF members and EU patient groups, in cooperation with learned societies and other stakeholders where appropriate as part of an EPF-led EU patient task force on information to patients on nutrition. The lay person summaries of recognised guidelines will be presented at the 2018 Conference for Optimal Nutritional Care for All (ONCA). For patient advocates to be able to contribute their unique experience and expertise in the sphere of nutrition, they need to understand key concepts and standards in this arena. The task force will also have the broader objective of raising awareness of the role of nutrition and diet in managing chronic and long-term conditions. Furthermore, the

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88 https://www.change.org/p/oui-au-nutri-score-sur-nos-aliments-non-aux-tentatives-de-brouillages-de-certains-industriels
89 https://european-nutrition.org/
task force will serve as a forum for different patient organisation to share their work, relevant initiatives and exchange and explore other priorities and actions linked to the topic of information to patients on nutrition.

EPF will also raise awareness of the role of nutrition and diet in managing long-term conditions, by disseminating this position statement on information to patients on food and nutrition and by developing further information materials and tools for patients and gathering patient stories.

In 2018, EPF will also support the co-creation and mutual endorsement of a code of conduct for the medical nutrition industry, with MNI and EPF as key drivers, that will enhance cooperation and interaction, on an ethical basis, between patients and the medical nutrition industry. This will draw on the considerable experience of EPF to date, in working with other sectors of the health industry. Such a code is a pre-requisite to ensure that, as the medical nutrition industry recognises and increasingly values the patient’s voice in all aspects of its work, that this is undertaken with the highest levels of integrity, ethics and independence.

EPF in coming years, aims to raise awareness of the importance of nutrition in managing long-term conditions and further explore the role of nutrition and diet in managing chronic conditions, maintaining optimal health and quality of life. EPF will work together with our members to this end. Advancing patient empowerment, we will continue our advocacy work on the importance of health literacy for patients and also for systems.

With this position statement, EPF advocates for a lifecycle approach to nutrition, affirming that nutrition has a significant role to play in the prevention, treatment and management of many chronic and long-term conditions, from pre-conception care to care of older people. The European Commission is planning to publish a report on innovative forms of food labelling by the end of 2018. This will be another opportunity to contribute the patient’s perspective and emphasise the importance of health literacy and informed decision-making concerning nutrition, and we will communicate further with our members about it.

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