

Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on the Impact of Consumption of Ultra-processed Foods on the Health of Consumers

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Working group

Pau Talens Oliag (Coordinator), Montaña Cámara Hurtado, Álvaro Daschner, Esther López García, Sonia Marín Sillué, José Alfredo Martínez Hernández and Francisco José Morales Navas

Scientific Committee

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Technical Secretary

Vicente Calderón Pascual

Abstract

Although at present there is no legal provision that establishes a specific definition for the concept of ultra-processed foods, attempts to improve public health have led to the emergence of different food classification systems based on the degree of processing. Of all the classification systems proposed, just two; the NOVA (Public Health School, Sao Paulo, Brasil) system and the SIGA system (France), use the term ultra-processed. The proposed definitions have been the source of some scientific dispute as some definitions refer to the type and degree of processing foods undergo while others refer to their formulation and composition. In this regard, it is important to remember that one cannot attempt to relate the degree of processing with an effect on health independently of the composition of the food. It is also important not to associate the term ultra-processed with foods of poor nutritional quality as this does not depend solely on the intensity or complexity of processing but the final composition of the food itself. Consequently, a more appropriate designation for the concept would be “processed foods of complex composition”.

Among the different food classification systems depending on the degree of processing, NOVA system has been used in most studies to analyze and document the effect of consumption of ultra-processed foods on various diseases or markers of disease, health or mortality.

Both transversal and longitudinal studies have been conducted, with many of these studies indicating that there does indeed exist a direct relationship between higher consumption of ultra-processed foods and cardiovascular diseases, obesity, type 2 diabetes, cancer and, in general, a greater risk of mortality. Despite that, it must be stressed that these studies are currently scarce and therefore there is a need for a more specific definition of ultra-processed food and to conduct more studies, allowing for the effect of these foods on the health of consumers to be assessed. Given that the effects on health seem to be attributed to certain food ingredients, it is considered necessary to study the impact of processed foods containing such ingredients on consumer health.

Existing studies demonstrate that dietary replacement of unprocessed with ultra-processed foods generates damaging effects on health, however, that is not evidence that replacement with “processed foods of complex composition” is more harmful than replacement with merely processed foods.

The Scientific Committee considers that, to justify the need for a differentiated category for ultra-processed foods or “processed foods of complex composition”, it would be necessary to conduct epidemiological studies that compare the impact on health of diets with a high consumption of processed foods containing those ingredients that appear to contribute to the generation of health problems, compared to diets based on processed foods that do not include such ingredients in their composition.

Keywords

Health, ultra-processed, NOVA, SIGA.

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1. Introduction

As a general rule, most reports, documents and publications relating to diet, nutrition and health are based on the classification of the nutritional profile and the chemical composition of foods. Today, however, many studies focus on classifying foods based on the degree of processing and, from there, evaluating the possible effect of the consumption of such foods (often designated as ultra-processed foods) on the health of consumers. Along this line, there have been a number of studies in different countries on the level of consumption of these types of food designated as ultra-processed (Monteiro et al., 2017) (Latasa et al., 2018) (Marrón-Ponce et al., 2018) and the relationship between their consumption and obesity (Filgueiras et al., 2018) (Nardocci et al., 2019) as well as related conditions such as diabetes, high blood pressure and hypercholesterolemia. This has given rise to the situation today whereby the expressions *processed foods* or *ultra-processed foods* are used frequently, often outside the scientific sphere, with negative connotations regarding their nutritional quality.

Given the lack of legal precision of the terms, extensive consumption of these types of foods among the Spanish population and their possible effects on health and the need to define these concepts in a detailed and precise manner for the design of public policies, the Scientific Committee of AESAN (Spanish Agency for Food Safety and Nutrition) has been requested to:

- Review key concepts and their corresponding definitions, the systems used for the classification of these types of foods, including the NOVA system, and determine whether the foods can be classified taking into account the degree of processing.
- Clarify, from a health impact perspective, whether the term ultra-processed refers to the degree of processing or the final composition of the food.
- Conduct an analysis of published scientific evidence in relation to the effects of consumption of ultra-processed foods on the health of consumers.

This report includes a review of the evidence published regarding the concept of ultra-processed foods, the food classification systems based on the degree of processing and the effect of their consumption on health.

2. Processing of foods

At present, there is no legal provision that establishes a specific definition for the concept of ultra-processed food. Regulation (EC) No. 852/2004 on the hygiene of foodstuffs (EU, 2004), explicitly states what is meant. By the terms processing, unprocessed products and processed products. It defines processing as any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes. It defines unprocessed products as foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed. It defines processed products as foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

The processing of foodstuffs is closely linked to anthropological aspects of human evolution. Ever since the domestication of fire by our ancestors, humans have been processing foodstuffs with the basic aim of preserving their organoleptic and nutritional and nutritional properties, in addition to eliminating/reducing biological risks, obtaining a microbiologically safe food while extending the shelf life. For example, the application of mild heating, pasteurization, guarantees the hygiene of the product through the elimination of harmful bacteria such as *Mycobacterium tuberculosis*, *Salmonella* spp. and *Staphylococcus aureus*, among others, as well as deactivating certain enzymes that might rapidly deteriorate organoleptic qualities in fresh products. Processing can also create new foodstuffs and drinks. For example, bread through the baking of a fermented cereal dough, coffee through the roasting of coffee beans making it possible to subsequently prepare the drink coffee or yoghurt through the fermentation of milk. However, the processing of foods may also imply a series of physical and biochemical modifications that, to a greater or lesser extent and depending on the food, confer new properties upon the prepared product. For example, increasing the digestibility of certain nutrients, increasing the accessibility of bioactive components, reducing the presence of anti-nutritional substances as well as improving palatability or providing a more attractive appearance, among other aspects. On the other hand, certain technological processes can constitute a partial or total loss of essential nutrients such as vitamins or amino acids or the formation of substances harmful to health such as heterocyclic amines. On other occasions, processed foods that include added sugar, salt or fat to extend shelf life or provide certain organoleptic characteristics can also have negative effects on the health of the consumer due to greater ingestion of these ingredients in the diet and increased calorie consumption from carbohydrates and fats, thus reducing the ingestion of proteins and vitamins and minerals.

Today it is common for the terms processed food or ultra-processed food to be used with negative connotations in relation to nutritional quality, but this is not always the case. In fact, it must be taken into account that many foods that are recommended for regular consumption require a stage of processing and in some cases several stages or processing. It is important to note, therefore, that just because a food is processed, it does not necessarily mean that it is damaging to one's health. In this regard, processed foods have both advantages and disadvantages compared to unprocessed foods.

3. Classification of foods according to their degree of processing

Regardless of the classification of foods established by Regulation (EC) No. 852/2004, the bibliography shows that there are currently seven possible food classification systems based on the degree of processing (Moubarac et al., 2014) (Fardet, 2015) (SIGA, 2017) (Monteiro et al., 2019). In most cases, the principal motivation for developing these classification systems is based on complementing epidemiological studies beyond the simple ingestion of nutrients to respond to the prevalence of overweight and obesity in the population in certain geographic areas and specifically in population groups such as infants and economically disadvantaged communities.

The seven classification systems are IARC-EPIC, IFIC, UNC, NIPH, IFPRI, NOVA and SIGA. In some cases, application is limited to one country (IFIC, UNC, NIPH, IFPRI), a geographic region (IARC-EPIC) or there are more global considerations (NOVA, SIGA).

The IARC-EPIC system was established in Europe in 2009 and subsequently updated in 2011 by the International Agency for Research on Cancer (IARC) using the methodology developed for the prospective European study on diet, cancer and health (EPIC) (Slimani et al., 2009) (Chajès et al., 2011). IARC-EPIC uses only the degree of processing as a factor for the classification of foods, establishing three main groups and various subgroups:

- Unprocessed foods consumed raw with no processing or operation other than washing, cutting or squeezing.
- Minimally or moderately processed foods, subdivided into:
 - Industrial and/or commercial foods consumed directly without cooking.
 - Foods processed at home and prepared/cooked from raw or minimally processed foods.
- Processed foods of industrial origin, divided into:
 - Basic diet processed foods or basic necessities.
 - Highly processed foods.

The IFIC system was designed by the US International Food Information Council Foundation (IFIC) of the United States along with food communication tools (Eicher-Miller et al., 2012), in response to the official US Dietary Guidelines issued in 2010, along with the North American Academy of Nutrition and Dietetics, the American Nutrition Society, the Institute of Food Technologies. The IFIC systems defines processing as any change deliberately made to a food from origin to the moment of consumption. The classification is based on the increased complexity of the processing of foods and the physical, chemical and sensory changes experienced by a food during processing. In this regard, foods are classified into five categories:

- Minimally processed foods that retain the majority of their inherent properties.
- Foods processed with the aim of assisting with better preservation of nutrients and organoleptic quality in its greater extension.
- Processed foods obtained from mixtures of combined ingredients that contain sweeteners, spices, oils, colourings, flavourings, and preservatives with the aim of providing safety, flavour or an attractive appearance, including those prepared at home.
- Ready-to-consume processed foods that require minimal or no preparation.
- Prepared foods and/or ready-to-eat meals.

The UNC system was developed by researchers at the University of North Carolina to study the contribution of processed foods to the ingestion of saturated fats, sugar and sodium on US households (Poti et al., 2015). Researchers define processed foods as those that are not raw agricultural materials, classified based on the extent of the physio-chemical changes undergone as a result of processing. Unlike other classification systems, the UNC system does consider a group apart comprised of those foods where technological processes are applied only with the aim of prolonging the shelf life of same, such as fermented and tinned products, cereals, refined or concentrate products. The UNC system was applied to register the foods acquired in over 150 000 homes (Poti et al., 2017). The UNC system classified foods based on type and composition of the ingredients, whether these

exceeded the recommended daily consumption and the extent of processing. The study concluded that 61 % of the energy of the US household shopping basket came from highly processed foods and drinks. Moreover, it was identified that the group of highly processed foods had a significantly higher content of saturated fats, sugar and sodium than moderately processed foods. At the outset seven categories were established and later some of those were reorganised into subcategories to harmonise the system with other classification systems, ending up with a classification of four groups (Bleiweiss-Sande et al., 2019):

- Unprocessed or minimally processed foods is the lowest category and includes food and drinks with just one ingredient that have not undergone modifications (or very light modifications) that do not change the inherent properties of the food in its raw, unprocessed form. These products are generally individual foods that may have components removed (e.g. Skin removed from poultry or fat skimmed from milk), but nothing added. The examples include fresh fruit, vegetables, milk, eggs and unseasoned meat.
- Foods with simple or basic processing. These are processed foods that maintain the reference with individual food. Two subcategories are established:
 - Foods processed from basic ingredients and may include sugar, oil or whole-wheat flour, but also isolated, extracted or purified components of unprocessed/minimally processed foods due to physical or chemical processes that can change the inherent properties of the food.
 - Foods processed or pre-cooked with the aim of guaranteeing conservation. They are unprocessed/minimally processed foods modified using conservation methods such as canning or grinding with the sole objective of maintaining hygienic stability or helping storage and transport.
- Foods subjected to moderate processing:
 - Moderately processed foods with added flavourings, aromas with the aim of improving flavour.
 - Moderately processed cereal-based foods prepared from whole-wheat flour, salt, water and/or yeast.
- Foods subjected to intense processing:
 - Foods formulated from a number of highly processed ingredients that are not recognisable in their original form.
 - Foods intensely processed from a complex formulation of ingredients not necessarily processed.

The NIPH classification system, developed by researchers at the National Institute of Public Health in Mexico (González-Castell et al., 2007), uses preparation and time period criteria, which allows for the distinction between industrialized and local foods and products and modern and traditional foods and products. The scope of application is local and restricted to Mexico. It divides foods into three categories:

- Modern industrialized foods introduced to Mexican diet recently.
- Traditional industrialized foods or ingredients that have been part of the traditional Mexican diet since before the 20th century but which are now mass produced.

- Non-industrialized foods, which are sub-divided into modern and traditional preparations made at home, traditional preparations made at home or artisanally, and unprocessed foods.

The IFPRI classification system was developed by a researcher at the International Food Policy Research Institute on Food Policies in Guatemala (Asfaw, 2011) with the aim of identifying the presence of processed foods in the food systems of countries with low income populations. Three categories of food are distinguished without differentiating between domestic and industrial processed foods, these being:

- Unprocessed foods that mostly include staple foods such as corn and other cereals, tubers, legumes, vegetables, fruit, fish, eggs and meat, etc.
- Partially processed foods from simple processing of raw or unprocessed foods.
- Highly processed foods, which are defined as those foods that are subjected to a second processing and that probably contain added sugars, hydrogenated fats (*trans*-fatty acids) and/or salt.

The NOVA system, developed in 2010 at the School of Public Health at the University of Sao Paulo, is a system that classifies foods based on the degree of processing, relegating the importance of composition in nutrients (Monteiro et al., 2010). One specific feature of the NOVA system is the consideration that all types of culinary preparations in the domestic environment are considered non-industrially processed foods and the classification only considers the characteristics of their ingredients. In general terms, the classification criteria are based on the nature, extension and purpose of industrial processing (Monteiro et al., 2012, 2016). At present, four groups are described, these being:

- Natural and minimally processed foods. These are foods of vegetable or animal origin consumed raw or subject to minimal processing (inclusion of ingredients or removal or parts thereof) that does not alter or modify the initial characteristics of the food.
- Processed culinary ingredients. This category refers to food products industrially extracted and purified from foods such as oil or obtained naturally, such as salt. The use of additives that might help the stability of processed culinary ingredients is also considered.
- Processed foods. For the preparation of these foods, the addition of other substances such as oils/fats, sugar or salt is required to enhance the stability or palatability of the product. In this category, the processing applied still allows for the identification of a significant part or all of the principal food.
- Ultra-processed foods and drinks. These foods have been prepared from different constituent foods, including additives (natural and synthetic), with the aim of extending their shelf life, greatly enhancing their palatability and acceptability of consumption. These are foods that can hardly be recognised regarding their original state.

The NOVA system has had different updates where, in principle, there was no differentiation between the intensity of processing, designating them as ready-to-eat processed foods. Nor was there any

specific distinction between the group of culinary ingredients (Monteiro, 2009). However, over time, the system was refined, and it was the first food classification system to introduce the term 'ultra-processed food', which is covered in-depth in section 4 of this report. The NOVA system indicates that the manufacture of ultra-processed food uses process such as pressing, extrusion or pre-frying, and therefore not possible to reproduce in a domestic environment or with the available elements and techniques. Moreover, ultra-processed foods are usually offered as ready-to-eat or drink products for consumption after simply heating them, thus replacing natural or minimally processed foods that are naturally ready-to-eat. Within the category of ultra-processed food are carbonated drinks; sweet or savoury pre-packaged sandwiches; ice creams, chocolate, confectionery products; pre-packaged mass-produced breads and pastries; margarines and spreads; biscuits, sponges, cakes, tarts and cake mixtures; breakfast bars; energy drinks; milk drinks, "fruit" yoghurts and "fruit" drinks; cocoa drinks; meat and chicken extracts and "instant" sauces; infant formula, follow-on milk, other baby products; "healthy" and "slimming" products such as meal replacement shakes and powders or "fortified" meals. Many ready-to-heat products including pasta and pizza dishes, fish, sausages, hamburgers, hot dogs and other reconstituted meat products, powdered and packaged "instant" soups, noodles and desserts and also snack products. Where products prepared only with natural or minimally processed foods and/or processed foods also contain flavour intensifier additives or any other sensory properties, such as natural yoghurts with added artificial sweeteners and breads with added emulsifiers, they are also included within this group. Similarly, alcoholic drinks produced by fermentation of natural foods followed by distillation of the resulting alcohol, such as whisky, gin, rum and vodka are also included.

The NOVA system is one of the most referenced in the literature (Lawrence and Baker, 2019) and has been applied in different countries (Australia applied the AUSNUT, the database of foods, nutrients and supplements) (O'Halloran et al., 2017), however, it has also been harshly criticised, claiming problems with the definition of the concept ultra-processed food: it does not define the limits of critical nutrients, nor is it clear what happens with legally authorised additives. Some examples do not meet the classification. They only allow for the tracking of individual foods within a category, but do not distinguish the ingestion of critical nutrients nor allow for the quantification of ingestion of micronutrients and it consists of a system that is the opposite of the commonly used classification systems such as FoodEx, EPIC or Langual (Gibney et al., 2017) (Quirós-Blanco and Incer-González, 2018).

Finally, the SIGA system was developed by a French start-up with the support of researchers at the University of Clermont Auvergne. This is a qualitative food quality classification system based on both the degree of processing reached in the application of processing and the use of additives (SIGA, 2017). Its promoters claim that this classification system makes progress on the NOVA system which now considers changes in the physical structure of the foods, and the nature and quantity of ingredients and/or additives added. The SIGA system is based on the approach that two foods with identical nutritional composition but with a different structure after processing would not have the same biological potential. The physical structure of the food influences the accessibility, digestibility and, consequently, the metabolism and biological function of the food ingredient (Fardet, 2015)

(Chambers, 2016). The SIGA system identifies three categories of foods with eight subgroups in total, these being:

- Unprocessed/minimally processed foods:
 - Group A0: Unprocessed (raw) foods where the structure of the food does not undergo changes. Peeled or cut food.
 - Group A1: Minimally processed foods where the original structure of the food has undergone a slight modification. The minimal use of additives is considered (no risk). Boiled, filtered, ground, powdered, pressed foods.
 - Group A2: Minimally processed foods including commonly used culinary ingredients.
- Processed foods:
 - Group B1: Processed foods with added salt, sugar and fats at levels in accordance with the official recommendations.
 - Group B2: Processed foods with added salt, sugar and fats at levels in excess of the official recommendations.
- Ultra-processed foods:
 - Group C1: Ultra-processed food that have lost their original structure and are formulated with unprocessed ingredients and/or up to a limited number of additives.
 - Group C2: Ultra-processed foods that have lost the original structure of the food and are formulated with processed ingredients and/or a high number of additives.
 - Group C3: Ultra-processed foods that have lost their original structure and are formulated with ultra-processed ingredients and/or a very high number of additives.

The SIGA system shares the three major concepts of NOVA (unprocessed/minimally processed, processed and ultra-processed) but also includes subdivisions according to the characteristics of the ingredients, the intensity of processing, the quantity of additives, the level of security and its function in the food. The scientific basis of SIGA is sustained by the French researcher Antony Fardet (University of Clermont-Auvergne, INRA, UNH-Unité de Nutrition Humaine, Clermont-Ferrand, France) (Fardet, 2015) (Fardet et al., 2018). Fardet argues that the nutritional potential of a food must be defined based on the structure of the food (qualitative aspect) and the composition of nutrients (quantitative aspect). One differentiating aspect of the SIGA classification system with regard to the others is its stable safety levels for the additives used, based on references of the EFSA (European Food Safety Authority), ANSES (*Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail*) and the WHO (World Health Organization), as well as a nutritional evaluation based on the references of the Food Standard Agency (FSA) of the United Kingdom. The SIGA system proposes a new, more defined paradigm of technological pyramid than NOVA, establishing differences between ultra-processed foods based on the type, quantity and function of the ingredient and/or additive used, as well as the intensity of the processing. One aspect that the SIGA developers underline is that, unlike NOVA, a grading system is established in the section on ultra-processed foods that is useful for the progressive reduction of their presence in one's diet through reformulation, changes in processing or the reduction of additives used. Figure 1 establishes the relations between most food

classification systems (NOVA, IFIC, IARC-EPIC, UNC, SIGA) described in this section. The NIPH and IFPRI are not considered here as their scope of application is more specific.

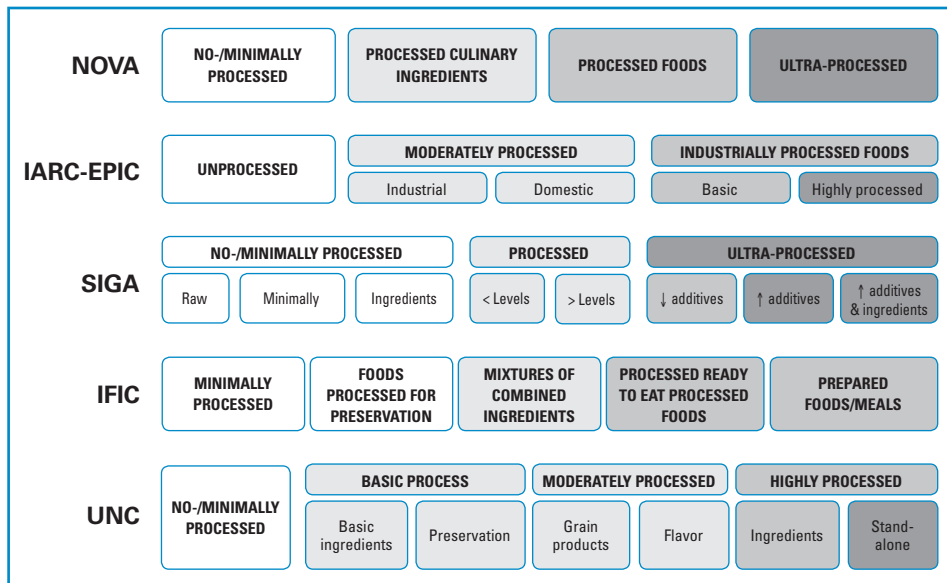


Figure 1. Principal food classification systems and their relationship with the degree of processing. Darker shading indicates greater intensity of processing and/or formulation complexity.

4. Concept of ultra-processed food

4.1 Concepts and terminology

The term “ultra-processed food” is relatively new. It was used in a publication for the first time in 2009 by Monteiro (comment in the journal *Public Health Nutrition*), which attempted to demonstrate the relationship between the transition from a diet based on minimally processed foods to one based on processed foods and the growth in obesity in Brazil. His argument was that the existing classifications, which group together foods in accordance with their nutrient profile, for example, meat and legumes as sources of protein, fruit and vegetables as sources of vitamins and minerals, cereals as sources of carbohydrates and energy, did not adjust to the approach to chronic, non-transmissible diseases. On the contrary, the degree of processing of foods could have an interest in relation to said illnesses, therefore, said publication proposed a classification (NOVA) into three groups:

- Group 1 was comprised of minimally processed foods, whole foods subjected to some processing that does not substantially alter the nutritional properties of the original foods which remain recognisable as such, while allowing for their preservation and making them accessible, convenient and sometimes safer and tastier. These processes include cleaning, removal of inedible parts, portioning, refrigeration, freezing, pasteurization, fermentation, pre-cooking, drying, skimming, bottling and packaging.

- Group 2 was substances extracted from whole foods. These include oils, fats, flour, pastes, starches and sugars. Mostly, they are consumed by themselves but traditionally they are ingredients used in domestic preparation and cooking of dishes comprised primarily of fresh and minimally processed foods.
- Group 3, ultra-processed foods, were foods comprised of substances from group 2 to which a minimum or relatively small quantity of minimally processed foods from group 1 is added, as well as salt and other preservatives, and often flavourings and colourings as well.

The foods from group 3 are considered more processed, given that they contain ingredients from group 2 which have previously been processed. However, under this definition a very high percentage of commonly consumed foods would be considered ultra-processed and, in addition, the heterogeneity from the nutritional perspective would be extensive. Consequently, Monteiro et al. (2010), noted: "The third group involves ultra-processed products that are ready-to-eat or ready-to-heat with little or no preparation. They are the result of the processing of various foods, including group 2 ingredients and unprocessed or minimally processed basic foods from group 1. Processes used in the production of group 3 products include salting, the addition of sugar, baking, frying, curing, smoking, pickling, canning and, frequently, the use of preservatives and cosmetic additives, the addition of synthetic vitamins and minerals and sophisticated forms of packaging". Furthermore, group 2 specifically included, for the first time, salt, fructose syrups, lactose, soy and milk proteins, and the processes involved were detailed: pressing, grounding, refining, hydrogenation, hydrolysis and the addition of enzymes and additives. The authors highlighted the processing of foods from group 2 which would be subsequently added to group 3 foods, given that processes detailed in group 3 are simple processes used traditionally in food processing.

In 2012, in light of the criticisms of a number of authors, arguing the low relevance of the classification from the nutritional perspective, Monteiro et al., updated the definition indicating that "ultra-processed products are not made from food but from ingredients. Some of these ingredients are derived from foods such as oils, fats, flour, starches and sugar but many are obtained from the additional processing of the components of the foods such as hydrogenated oils, hydrolysed proteins, modified starches and meat offcuts extruded or processed in another manner. Numerically, most ultra-processed ingredients are additives of a variety of types that include, among others, preservatives, stabilizers, emulsifiers, solvents, binders, bulkers, sweeteners, sensory enhancers, flavours and colours. The function of many of these is to make the product look, smell, feel and taste like food". This is a definition that contradicts Regulation (EC) No. 178/2002 where food is described as "any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans" and ingredient as "any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as ingredients" (EU, 2002).

This way, Group 3 (Food products) was divided into three: processed foods, alcoholic drinks, and ultra-processed foods. The ultra-processed food group therefore excludes a series of foods due

to the fact that a more recognisable raw material exists and only salt, sugar, oils and non-modified fats are used from group 2. In the case of conserved vegetables and fish, fruit in syrup, processed meats such as serrano ham or bacon, smoked fish or cheese. Therefore, for inclusion in the group of ultra-processed foods, the determining factor is the presence of group 2 ingredients derived from hydrogenation, hydrolysis, enzymatic treatment or extrusion but not refining or milling.

In 2015, Poti et al. (2015), defined highly processed food and drink as “multi-ingredient mixtures, formulated industrially, processed to the point that the animal or vegetable origin is no longer recognisable” The study showed that moderately and highly processed foods contained higher levels of saturated fats, sugars and sodium than minimally processed foods. However, differences between moderately and highly processed foods were not analysed, even though highly processed foods presented, on average, a greater concentration of sugar.

Subsequently, Louzada et al. (2015), with Monteiro as co-author, would define ultra-processed foods as “products ready to consume that are comprised entirely or principally of substances extracted from foods (oils, fats, sugar, protein), derived from food components (hydrogenated fats, modified starches) or synthesized based on organic materials (colourings, aromas, flavour enhancers and other additives used to alter the sensory properties of foods)”. In 2016, ultra-processed foods were classified separately in Group 4, while processed foods and alcoholic drinks remain in group 3 (Monteiro et al., 2016). In 2016, the detail “industrial formulations typically with five or more and generally many ingredients in the definition” was also included in the definition of ultra-processed foods. Many of the ingredients are common in processed foods, although it is indicated that “the ingredients that are only found in ultra-processed products are additives whose purpose is to imitate the sensory qualities of group 1 foods or culinary preparations of these foods, or to disguise undesirable sensory qualities of the final products or some substances extracted directly from foods, such as casein, lactose, whey and gluten and some derivatives of the subsequent processing of the components of the foods, such as hydrogenated oils or intensifiers, hydrolysed proteins, soy proteins, maltodextrin, inverted sugar and high-fructose corn syrup”. It is also noted that in the manufacture of ultra-processed products, various industrial processes with no domestic equivalent are used, such as extrusion (included in the definition of processing in Regulation (EC) No. 852/2004) and moulding and pre-processing for frying.

Finally, in 2018, Monteiro et al. (2018), defined ultra-processed foods as “industrial formulations produced from substances obtained from foods or synthesized from other organic sources. They normally contain little or no intact food, are prepared for consumption or heating and are rich in fats, salt or sugars and poor dietary fibre, protein, various micronutrients and other bioactive compounds”. The document itself states that a practical way of identifying an ultra-processed product is to verify if the ingredient list contains at least one element characteristic of the ultra-processed foods group, that is, food substances that are never or rarely used in kitchens or types of additives designed to make the final product appetizing or attractive such as flavourings, flavour enhancers, colourings, emulsifiers, emulsion salts, colourings, thickening agents, anti-foaming agents, gelling and glazing agents (Monteiro et al., 2019). In conclusion, in this new update to the NOVA classification system, processing was pushed to second place, while the presence of additives together with use of certain

group 2 ingredients: casein, lactose, whey, gluten, modified starches, hydrogenated or interesterified oils, hydrolysed proteins, soy proteins, maltodextrin, inverted sugar and high-fructose corn syrup, and extruded meat products, were determining factors for a food to be considered ultra-processed.

Fardet's definition (2018) is along the same lines. For Fardet, ultra-processing consists of the fractioning of foods and the subsequent recombination of ingredients/nutrients to produce "artificial foods" with numerous additives. Examples of the unstructured ingredients include purified, fractioned and/or highly processed ingredients, fructose-glucose syrups or isolated, purified and/or hydrolysed proteins. The authors hypothesize that, despite the fact that they have the same compositions in terms of carbohydrates and calories, consuming whole sugar cane is not the same as consuming refined table sugar or fructose or glucose syrup. Therefore, the fractioning of foods or ingredients is the first common attribute and is very characteristic of ultra-processed foods. They also point out the effect of the structure or the food matrix. It is necessary to combine both the "matrix" and the "composition" effect, the "matrix" being the qualitative and holistic fraction of the foods, which comes first because we eat matrices first and not nutrients and the "composition" is the quantitative and reductionist fraction which comes second. According to the authors, the potential effect on health of ultra-processed foods must be assessed with respect to this definition because two foods with the same composition but with different structures, do not have the same effect on health (Fardet et al., 2019). However, when said authors (Fardet et al., 2018) assessed the properties of minimally processed, processed and ultra-processed foods, they found no differences between processed and ultra-processed foods (except for the number of ingredients and/or additives), while both were differentiated from minimally processed foods. Properties such as fracture energy and maximum stress (textural aspects), satiating factor, nutrient density, number of ingredients and/or additives, the percentage with respect to recommended maximum values on concentration of sodium, saturated fatty acids and sugars (LIM index: Limited nutrient score) showed the difference between minimally processed and processed foods, but processed foods were no different from ultra-processed foods. The same authors concluded that ultra-processed foods have a higher glycemic index and a lower satiating power: ultra-processed foods include many liquid and semi-solid foods, which are less satiating than solid foods and contain less fibre and protein, which also makes them less satiating.

Researchers most critical of the term "ultra-processed food" claim that the definition does not refer to processing nor to unitary operations used during the production of the food products described but rather that it is a question of formulation and composition. With said definition, a combination of unprocessed or minimally processed foods and processed ingredients result in ultra-processed foods without any additional processing. Consequently, this would mean that the use of additives, rather than appropriate processing of raw agricultural material foods, determines the characteristics of ultra-processed foods (Knorr et al., 2019).

4.2 Limitations of food classification systems based on the degree of processing

Based on the current definitions of ultra-processed foods, it is important to note that the term ultra-processed should not be associated with the intensity of the degree of processing of a food nor

the low nutritional quality of the product. We can find examples relating to the intensity of processing in products like coffee, bread, yoghurt or carbonated drinks. Regarding coffee, the NOVA classification includes the roasted coffee bean with no added sugar in group 1 (unprocessed/minimally processed foods) as it considers roasting a necessary process allowing its consumption (Monteiro et al., 2017). However, coffee roasting is among the highest intensity processing technologies that can be applied to a food, drastically modifying the physiochemical characteristics thereof, reaching temperatures in excess of 200 °C for several minutes. In this case, treatment intensity is not sufficient to catalogue the food as ultra-processed. The NOVA classification would only consider instant coffee to be an ultra-processed food (Moubarac et al., 2014) as it is obtained through the freeze-drying/evaporation of a coffee drink concentrate. Bread is another example. While bread comprised of wheat flour, water, salt and yeast would be a processed food, when it includes emulsifiers, it would be considered an ultra-processed food, even though the degree of processing is the same, modifying only the formula. Similarly, natural yoghurt is considered processed food, but if colourings or aromas are added it is considered ultra-processed food. Carbonated drinks, despite being formulated using a high number of ingredients, undergo simple processing, based on mixing different ingredients, subsequent carbonation and packaging; although even still, they are classified as ultra-processed.

Examples of why food classified as ultra-processed should not be associated with low nutritional quality can be found for different foods present on the market. If we consider, for example, a ready-to-eat vegetable soup, this food would be classified as ultra-processed. However, its nutritional value will depend on its salt, sugar and fat content among others, meaning that while it remains ultra-processed it may be nutritionally correct or not. The same occurs with other examples such as chickpea hummus or canned marinated mussels. Another example can be found in infant formula. Infant formula is based on the fractioning and subsequent recombination of foods and is therefore considered an ultra-processed food, despite the fact that specific processing includes only drying as the most intense process and these products cannot be considered products of low nutritional quality. In this example, it is important to highlight that infant formula does not have better nutritional quality than maternal milk, but it can be stated that if there is a need for infant formula, one can be certain that even though it is an “ultra-processed food”, it is not a food with low nutritional quality. Finally, a large number of processed (and ultra-processed) foods exist that are fortified in vitamins and minerals, the positive effect of which from a nutritional perspective must be taken into account.

5. Ultra-processed foods and health

It is important to underline that no studies relating to the risk to health were found to use the IFIC, NIPH or SIGA classifications. These systems have only been used to analyse the contribution to calorie and nutrient intake according to the processing of foods (Eicher-Miller et al., 2015) and for data on the contribution processed foods in the general American or Mexican population, respectively (González-Castell et al., 2007) (Eicher-Miller et al., 2012). With regard to the IFPRI classification system, only the Asfaw (2011) publication is available, which identifies how an increase of 10 % in consumption of highly processed foods increases a person's BMI by 4.25 %. The NOVA system is used in most studies with the aim of analysing and documenting the effect of consumption of ultra-pro-

cessed foods on several diseases or markers of disease, health or mortality.

Consumption of ultra-processed foods is widespread in most countries. Studies conducted in the United States show that ultra-processed foods included 91 % of the cereal products consumed in the country, 73 % of fats and sweets, 71 % of the dairy products, 71 % of legumes, nuts and seeds but only 36 % of meat, poultry and fish, 26 % of vegetables and 20 % of fruit. In total, ultra-processed foods represent 57.4 % of the average diet, while 7.3 % were processed foods and 33.2 % were unprocessed or minimally processed foods (Gutpa et al., 2019). In comparison with unprocessed foods, ultra-processed foods had lesser nutrient density and greater density of energy and were deficient in nutrients (Gupta et al., 2019). For all that, ultra-processed foods are considered markers of a poor-quality diet (Tapsell et al., 2016).

It is important to understand the effect of ultra-processed foods on health as some changes introduced to food processing in the past, aimed at improving their properties, have led to paradoxical situations. For example, the increase in ingestion of *trans* fatty acids where partially hydrogenated vegetable oils were promoted as a substitute ingredient for animal-based saturated fats when at present it is known that *trans* fats are more harmful to health than saturated fats. Another example is the replacement of fat with sugar in the manufacturing of processed foods low in fat, which is currently questioned (Scrinis and Monteiro, 2018).

The research on the effect of ultra-processed foods on health had been tackled in a number of studies in the past looking at each of them on a separate basis. Thus, the effect of sugary drinks on the onset of type 2 diabetes, heart disease and premature mortality had been subject to study (Malik et al., 2010, 2019). The effect of high consumption of processed meat and its association with higher risk of gastric cancer is also well established (González et al., 2010). However, with the emergence of classifications based on the degree of processing, the effect of consumption of ultra-processed food overall is beginning to be studied, using different methodological approaches.

5.1 Ultra-processed foods and risk of cardiometabolic disease, cancer and premature mortality

Most existing evidence comes from transversal studies, that is to say studies where diet and fluctuations in health are measured at the same time and, therefore, they are not capable of demonstrating causality. In a review of nine studies, five of which were transversal, it was concluded that there existed a link between high consumption of ultra-processed foods and greater prevalence of obesity (Poti et al., 2017). Another work with similar design, sought food patterns that would predict weight changes in study subjects, and found that a pattern of high consumption of processed or ultra-processed foods such as processed meats, butter, fatty cheese, margarine and meat, was predictive of increased weight (Schulz et al., 2005).

A subsequent Danish study with 20 835 participants deemed overweight or obese observed that a pattern with high index of ingestion of sugary drinks, fried snacks and low consumption of fruit and vegetables was associated with a high risk of type 2 diabetes (Bauer et al., 2013). A different approach was used to identify dietary patterns that were capable of predicting type 2 diabetes; the authors used a case-control design 192 newly diagnosed patients and 382 controls. Cases had a pattern of

low consumption of fresh fruit and high consumption of sugary drinks, beer and red and processed meats (Heidemann et al., 2005).

Longitudinal studies, with monitoring of participants over years to detect health problems arising from regular consumption of ultra-processed foods are currently scarce. Studies published on the link between consumption of ultra-processed foods and risk of mortality, cancer and heart disease are summarised in table 1.

Table 1. Prospective studies that have examined consumption of ultra-processed foods and the risk of mortality, cancer and heart disease (*)

Authors, year	Type of study	Definition of ultra-processed	No. participants	Outcome variable	Conclusion
Rico-Campà et al. (2019)	SUN cohort, Spain	NOVA System	19 899	Death by any cause (n events= 335)	Consumption of >4 portions/day, compared to zero consumption per day was associated with an increase in mortality of 62 %
Kim et al. (2019)	NHANES III, United States	NOVA System	11 898	Death by any cause (n events= 2451)	Higher consumption of ultra-processed foods (upper quartile vs. lower quartile) was associated with a 31 % increase in mortality risk
Schnabel et al. (2019)	NutriNet-Santé cohort, France	NOVA System	44 551	Death by any cause (n events= 602)	An increase of 10 % in ultra-processed foods was associated with a mortality risk of 14 %
Blanco-Rojo et al. (2019)	ENRICA cohort system, Spain	NOVA System	11 898	Death by any cause (n events= 440)	Higher consumption of ultra-processed foods (upper quartile vs. lower quartile) was associated with a 44 % increase in mortality risk
Fiolet et al. (2018)	NutriNet-Santé cohort, France	NOVA System	104 980	Cancer by any cause (n events= 2228), breast cancer (n events= 739)	An increase of 10 % in consumption of ultra-processed foods was associated with a risk of cancer by any cause of 12 % and a risk of breast cancer of 11 %
Srouf et al. (2019)	NutriNet-Santé cohort, France	NOVA System	105 159	Total cardiovascular disease (ECV, n events= 1409), heart disease (EC, n events= 665), cerebrovascular disease (n events= 829)	An increase of 10 % in consumption of ultra-processed foods was associated with a risk of cardiovascular disease and heart disease of 12 % and a risk of cerebrovascular disease of 11 %

(*) Of all the studies available relating to health or mortality with ingestion of ultra-processed foods, those with the most evidence are displayed for their prospective nature. Up until now, the NOVA system has been the only system for which results have been obtained with these criteria, and are in factory recent (years 2018 and 2019).

NutriNet-Santé was a prospective observational study (open cohort) that began in France and Belgium in 2009 (NutriNet-Santé, 2009). Among other issues, it studies the relationship between the ingestion of foods, nutrients, dietary behaviour and mortality, incidence of cancer, cardiovascular disease, obesity, type 2 diabetes, dyslipidaemia, metabolic syndrome and ageing (NutriNet-Santé, 2009). Other analysis investigated the risk of cancer, for which the data of 104 980 participants aged over 18 were analysed, here too, NOVA classification allowed dietary patterns comparison. An association was found between the ingestion of ultra-processed foods with risk of cancer in general and breast cancer (Fiolet et al., 2018). The contribution of ultra-processed foods to the complete diet of the individual subjects of the study was 18.7 % (18.74 % for men and 18.71 % for women). Figure 2 describes the contribution of the principal food groups to ingestion of ultra-processed foods and the NutriNet-Santé study (Fiolet et al., 2018).

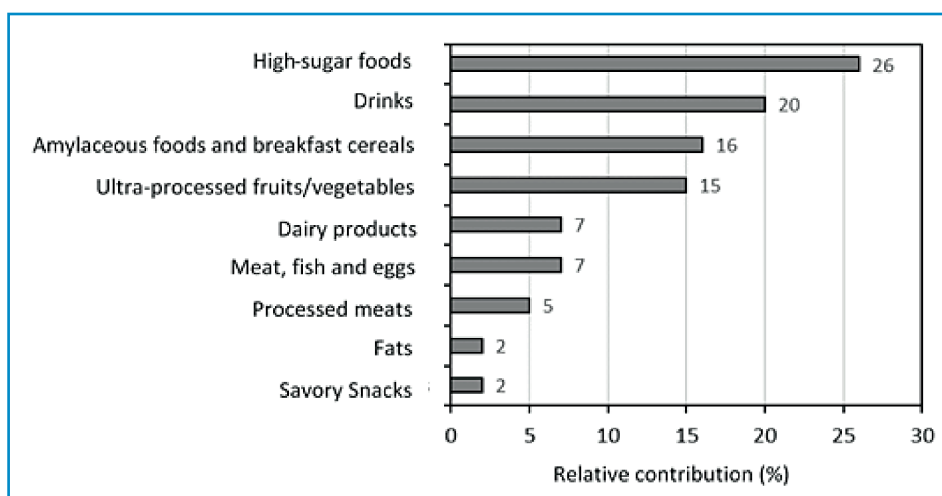


Figure 2. Relative contribution of each food group to the consumption of ultra-processed foods. NutriNet-Santé study. **Adapted from:** Fiolet et al. (2018).

The SUN cohort began in 1999 and has more than 22 500 participants. It is a cohort that investigates the causes of obesity, cardiovascular diseases, arterial hypertension, diabetes, metabolic syndrome, depression, traumas, infertility and other conditions. It included analysis of 14 970 university students to observe the incidence of arterial hypertension after an average of 9.1 years. Participants in the upper tercile of ultra-processed foods according to the NOVA classification had a higher mortality risk (Rico-Campà et al., 2019). When they studied the association between ultra-processed foods and cardiovascular disease risk factors, higher consumption of these foods was associated with greater risk of high blood pressure (Mendonça et al., 2017), overweight and obesity (Mendonça et al., 2016). The authors of these studies reflected in the study limitations that, while the questionnaire was used for classification of foods according to the NOVA criteria, it was not specifically designed for the classification of food according to its processing, which could underestimate or overestimate consumption of ultra-processed foods.

Other cohorts that have examined the effect of ultra-processed foods are the NHANES cohorts in the United States and the ENRICA cohorts in Spain. In both cases, elevated consumption of these foods was associated with greater risk of premature mortality.

5.2 Ultra-processed foods and other effects on health

In another study of the Nutri-Santé cohort (Schnabel et al., 2018), 33 343 participants were analysed, in which ultra-processed foods according to the NOVA classification accounted for 16 % of the foods in terms of weight and 33 % of the calorie intake. After analysing possible confounding factors, an increase in ingestion of ultra-processed foods was associated with an elevated risk of irritable bowel syndrome (OR: 1.24, 95 % CI: 1.12-1.39, $p < 0.001$).

With data on the Spanish ENRICA cohort, which consists of a representative sample of the Spanish adult population, it has been found that high consumption of ultra-processed food (upper quartile vs. lower quartile) was associated with a greater risk of fragility or a geriatric syndrome precursor of disability (Sandoval-Insausti et al., 2019). Moreover, in the SUN cohort, people within the highest quintile for consumption of ultra-processed foods had a 33 % higher risk of depression than those in the lowest consumption quintile (Gómez-Donoso et al., 2019).

Allergic diseases and bronchial asthma are chronic inflammatory illnesses and the significant increase in prevalence of these in recent decades has led to the study of lifestyle factors. Two recent publications include the concept of ultra-processed food. The most important sample was one of 109 104 Brazilian adolescents, based on a questionnaire solely focussed on questions on ultra-processed products consumption (sweet or savoury biscuits, sweets, ultra-processed meats, sugary drinks and industrial snacks) for a week. Comparing the extreme categories, odds ratios were found for the risk of asthma or wheezing, between 1.08 and 1.3 for each separate product. On a scale bringing together all the ultra-processed products, the risk of asthma and wheezing comparing the upper quintile with the lower was 1.27 (1.15-1.41) and 1.42 (1.35-1.50), respectively (Melo et al., 2018). Another study of smaller dimensions was conducted, on a prospective basis, with 2190 children aged between 6 and 11. Responses were obtained on consumption in the last 24 hours via a semi-quantitative questionnaire on the frequency of consumption of foods and these were then classified in accordance with the NOVA system. No significant associations for the incidence of asthma or wheezing after 5 years (Machado-Azeredo et al., 2019). The authors recognise as a weakness of the study the fact that questionnaires were not prepared with the intention of classifying all foods according to the degree of processing.

A study published in California in 2015 analysed the frequency of consumption of fast food during pregnancy, observing the incidence of wheezing or asthma in their children of 3.5 years of age. In a dose-dependent response and in comparison with those who never ate fast food, those who ate it once a week, 3-4 times a week or daily were diagnosed with asthma with a relative risk of 1.26, 2.17 and 4.46, respectively (von Ehrenstein et al., 2015).

In a sub-analysis, the ISAAC (phase III) study on asthma and allergies in infancy also provided similar data. So, of the 143 967 children analysed, consumption of fast food (<1; 1-2 times; >3 times/week) was associated with a higher prevalence of wheezing in adolescents (OR: 1.32; 1.22-1.43) (Cepeda et al., 2017). Here, the questionnaire was not specific according to the degree of processing either.

In addition to epidemiological studies mentioned, we must add epidemiological studies that review the potential impact of ultra-processed foods on auto-immune diseases. In this regard, a review and analysis by Aguayo-Patrón and Calderón de la Barca (2017) provides details on how various nutrients (and additives) of ultra-processed foods could be involved in increasing the risk of developing type 1 diabetes or coeliac disease through the increase of pro-inflammatory responses induced from the gastrointestinal tract. What is interesting about the approach of this review is that it involves intestinal microbiota through a dysbiosis in the development of the risk of disease.

5.3 Biological mechanisms

The biological mechanisms that demonstrate a possible harmful effect of ultra-processed foods beyond that associated with their nutritional composition, are yet to be accurately identified. It has been suggested that these foods could be “hyperpalatable”, that is to say that their combination of nutrients makes them especially appetising and this leads to excessive consumption, with low satiating power, as would be the case with sugary drinks, where it has been speculated that “liquid” calories are not capable of triggering the satiating mechanisms of the body and that they produce addiction (Gibney et al., 2017). However, many of these evidences are based on experimental studies in animals and have not been sufficiently investigated. Furthermore, the processing of food has a different effect on each type of macronutrient. The processing of carbohydrates makes their digestion faster and leads to spikes in glycaemia and insulinaemia that have been associated with a higher risk of cardiometabolic alterations (Ludwig and Ebbeling, 2018). On the contrary, the processing of proteins and fats does not appear to have an impact on the metabolism of these nutrients. Finally, other authors (Zinöcker and Lindseth, 2018) indicate that ultra-processed foods affect intestinal microbiota, increasing their pro-inflammatory potential.

Conclusions of the Scientific Committee

The AESAN Scientific Committee, having reviewed the evidence published in relation to the concept of ultra-processed food, food classification systems based on the degree of processing and the effect of their consumption on health, has reached the following conclusions:

Systems used for the classification of foods based on the degree of processing

Regardless of the classification of food set out in Regulation (EC) No. 852/2004, which establishes a distinction between unprocessed foods and processed foods, at present we can find seven possible classification systems in the bibliography based on the degree of processing: the IARC-EPIC system (European scope), the IFIC and UNC system (United States), the NIPH system (Mexico), the IFPRI system (Guatemala), the SIGA system (France) and the NOVA system (Brazil).

Review of the key concepts and corresponding definitions

Of all the food classification systems based on the degree of processing, two of them; the NOVA system and the SIGA system, use the term ultra-processed food despite the fact that there is no legal provision that establishes a specific definition. The definitions proposed for the term ultra-processed

food have generated considerable dispute in the scientific sphere, not only because they have been amended over time, but also because of the lack of homogeneity in the application of unified classification criteria. In some cases, the definition of ultra-processed foods refers to the type and degree of processing the food undergoes and in other cases to the formulation and composition.

Taking into account the definition of transformed or processed food according to Regulation (EC) No. 852/2004, it is concluded that, in accordance with the regulation in force, most foods designated as ultra-processed in these classification systems really meet the definition of processed foods.

Classification of foods taking into account the degree of processing

In relation to the type of processing, it is important to note here that this definition should not be associated with the intensity of processing a food undergoes.

It is important to remember that it is not possible to relate the degree of processing with health independently of the composition of the food, as it is demonstrated that there is no correlation between degree of processing and the number of ingredients present in a food defined as ultra-processed and its nutritional quality.

Ultra-processed aspect is attributed if a food contains additives; the use of additives is subject to regulation derived from risk analysis, and therefore its mere inclusion cannot be linked to nutritional harm.

Consequently, a more appropriate designation for what it is sought to define would be “processed foods of complex composition”.

Effect of consumption of “ultra-processed” foods on health

It is important not to associate the term ultra-processed with products low in nutritional quality as this does not depend solely on the intensity or complexity of processing but on the final composition of the food.

Of the different food classification systems based on the degree of processing, the NOVA system is the one used in most studies with the aim of analysing and documenting the effect of consumption of ultra-processed foods on several diseases or markers of disease, health or mortality. Both transversal and longitudinal studies have been conducted, with many of these studies indicating that there does indeed exist a direct relationship between higher consumption of ultra-processed foods and cardiovascular diseases, obesity, type 2 diabetes, cancer and, in general, a greater risk of mortality. Despite that, it must be underlined that these studies are currently scarce and therefore, there is a need to define ultra-processed food and conduct more studies that allow evaluation of the effect of these foods on the consumers.

Given the focus appears to be on certain food ingredients such as casein, lactose, whey, gluten, modified starches, hydrogenated and interesterified oils, hydrolysed proteins, soy proteins, maltodextrin, inverted sugar and high-fructose corn syrup, and extruded meat products, the study of the impact of consumption of processed foods including such ingredients on health is considered necessary.

Existing studies demonstrate that the replacement of unprocessed foods in one's diet with ultra-processed foods generates damaging effects on health, however, that does not demonstrate

that replacement with “processed foods of complex composition” is more harmful than replacement with merely processed foods.

The scientific Committee considers that, to justify the need for a differentiated category for ultra-processed foods or “processed foods of complex composition”, it would be necessary to conduct epidemiological studies that compare the impact on health of diets with a high consumption of processed foods containing those ingredients that appear to contribute to the generation of health problems, compared to diets based on processed foods that do not include such ingredients in their composition.

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